Australian Government
Department of Health

PBS

# Schedule of Pharmaceutical Benefits

**Effective 1 October 2017**

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

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

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# Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 October 2017 and are included, where applicable, in prices published in the Schedule —

| | | |
|---|---|---|
| Dispensing Fees: | Ready-prepared | $7.15 |
| | Dangerous drug fee | $3.01 |
| | Extemporaneously-prepared | $9.19 |
| | Allowable additional patient charge* | $4.38 |
| Additional Fees (for safety net prices): | Ready-prepared | $1.21 |
| | Extemporaneously-prepared | $1.57 |
| Patient Co-payments: | General | $38.80 |
| | Concessional | $6.30 |
| Safety Net Thresholds: | General | $1494.90 |
| | Concessional | $378.00 |
| Safety Net Card Issue Fee: | | $9.73 |

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

# Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 October 2017. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

## Prescriber Bag

### Deletions

***Deletion – Brand***

3496B *Ventolin Nebules, GK* – **SALBUTAMOL**, salbutamol 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

## General Pharmaceutical Benefits

### Additions

***Addition – Item***

11187T **ALPRAZOLAM**, alprazolam 500 microgram tablet, 10 *(Alprax 0.5)*

11186R **ALPRAZOLAM**, alprazolam 1 mg tablet, 10 *(Alprax 1)*

11185Q **AMINO ACID FORMULA WITH VITAMINS AND MINERALS, LOW PHENYLALANINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID AND ARACHIDONIC ACID**, amino acid formula with vitamins and minerals, low phenylalanine and supplemented with docosahexaenoic acid and arachidonic acid powder for oral liquid, 30 x 12.5 g sachets *(PKU Anamix First Spoon)*

2022K **AURANOFIN**, auranofin 3 mg capsule, 60 *(Ridaura)*

11189X **BREXPIPRAZOLE**, brexpiprazole 1 mg tablet, 30 *(Rexulti)*

11188W **BREXPIPRAZOLE**, brexpiprazole 2 mg tablet, 30 *(Rexulti)*

11190Y **BREXPIPRAZOLE**, brexpiprazole 3 mg tablet, 30 *(Rexulti)*

11184P **BREXPIPRAZOLE**, brexpiprazole 4 mg tablet, 30 *(Rexulti)*

***Addition – Brand***

2019G *ZETIN, RW* – **ACITRETIN**, acitretin 10 mg capsule, 100

2020H *ZETIN, RW* – **ACITRETIN**, acitretin 25 mg capsule, 100

5551E *Bimatoprost Sandoz, SZ* – **BIMATOPROST**, bimatoprost 0.03% eye drops, 3 mL

8620Q *Bimatoprost Sandoz, SZ* – **BIMATOPROST**, bimatoprost 0.03% eye drops, 3 mL

3190X *APO-Ibuprofen 400, TX* – **IBUPROFEN**, ibuprofen 400 mg tablet, 30

3192B *APO-Ibuprofen 400, TX* – **IBUPROFEN**, ibuprofen 400 mg tablet, 30

5123P *APO-Ibuprofen 400, TX* – **IBUPROFEN**, ibuprofen 400 mg tablet, 30

5124Q *APO-Ibuprofen 400, TX* – **IBUPROFEN**, ibuprofen 400 mg tablet, 30

5449T *Ataris 10, AF* – **LEFLUNOMIDE**, leflunomide 10 mg tablet, 30

8374R *Ataris 10, AF* – **LEFLUNOMIDE**, leflunomide 10 mg tablet, 30

5450W *Ataris 20, AF* – **LEFLUNOMIDE**, leflunomide 20 mg tablet, 30

8375T *Ataris 20, AF* – **LEFLUNOMIDE**, leflunomide 20 mg tablet, 30

8839F *Artige, NM* – **METHYLPHENIDATE**, methylphenidate hydrochloride 10 mg tablet, 100

9365X *MIRTANZA, RF* – **MIRTAZAPINE**, mirtazapine 15 mg tablet, 30

8513C *MIRTANZA, RF* – **MIRTAZAPINE**, mirtazapine 30 mg tablet, 30

8883M *MIRTANZA, RF* – **MIRTAZAPINE**, mirtazapine 45 mg tablet, 30

8816B *Modafinil Mylan, AF* – **MODAFINIL**, modafinil 100 mg tablet, 60

1653B *Morphine MR Mylan, AF* – **MORPHINE**, morphine sulfate 10 mg modified release tablet, 28

1654C *Morphine MR Mylan, AF* – **MORPHINE**, morphine sulfate 30 mg modified release tablet, 28

1655D *Morphine MR Mylan, AF* – **MORPHINE**, morphine sulfate 60 mg modified release tablet, 28

1656E *Morphine MR Mylan, AF* – **MORPHINE**, morphine sulfate 100 mg modified release tablet, 28

8385H *Novacodone, HX* – **OXYCODONE**, oxycodone hydrochloride 10 mg modified release tablet, 28

8386J *Novacodone, HX* – **OXYCODONE**, oxycodone hydrochloride 20 mg modified release tablet, 28

8387K *Novacodone, HX* – **OXYCODONE**, oxycodone hydrochloride 40 mg modified release tablet, 28

8388L *Novacodone, HX* – **OXYCODONE**, oxycodone hydrochloride 80 mg modified release tablet, 28

8814X *APOHEALTH Osteo Relief Paracetamol 665 mg, TX* – **PARACETAMOL**, paracetamol 665 mg modified release tablet, 96

2242B *APO-Paroxetine, TX* – **PAROXETINE**, paroxetine 20 mg tablet, 30

8363E *Raloxifene AMNEAL, ED* – **RALOXIFENE**, raloxifene hydrochloride 60 mg tablet, 28

10551H *MAXATAN, RW* – **RIZATRIPTAN**, rizatriptan 10 mg orally disintegrating tablet, 2

### *Addition – Equivalence Indicator*

5551E *Lumigan, AG* – **BIMATOPROST**, bimatoprost 0.03% eye drops, 3 mL

8620Q *Lumigan, AG* – **BIMATOPROST**, bimatoprost 0.03% eye drops, 3 mL

3190X *Brufen, GO* – **IBUPROFEN**, ibuprofen 400 mg tablet, 30

3192B *Brufen, GO* – **IBUPROFEN**, ibuprofen 400 mg tablet, 30

5123P *Brufen, GO* – **IBUPROFEN**, ibuprofen 400 mg tablet, 30

5124Q *Brufen, GO* – **IBUPROFEN**, ibuprofen 400 mg tablet, 30

8839F *Ritalin 10, NV* – **METHYLPHENIDATE**, methylphenidate hydrochloride 10 mg tablet, 100

### *Addition – Note*

2131E **ALPRAZOLAM**, alprazolam 500 microgram tablet, 50 *(Alprax 0.5, Kalma 0.5)*

2132F **ALPRAZOLAM**, alprazolam 1 mg tablet, 50 *(Alprax 1, Kalma 1)*

11178H **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial *(Stelara)*

## Deletions

### *Deletion – Item*

1085D **CEFOTAXIME**, cefotaxime 1 g injection, 1 vial *(Cefotaxime Sandoz)*

5048Q **CEFOTAXIME**, cefotaxime 1 g injection, 1 vial *(Cefotaxime Sandoz)*

1581F **HUMAN CHORIONIC GONADOTROPHIN**, human chorionic gonadotrophin 1500 units injection [3 ampoules] (&) inert substance diluent [3 x 1 mL ampoules], 1 pack *(Pregnyl)*

### *Deletion – Brand*

9049G *Chem mart Amlodipine/Atorvastatin 5/10, CH* – **AMLODIPINE + ATORVASTATIN**, amlodipine 5 mg + atorvastatin 10 mg tablet, 30

9049G *Terry White Chemists Amlodipine/Atorvastatin 5/10, TW* – **AMLODIPINE + ATORVASTATIN**, amlodipine 5 mg + atorvastatin 10 mg tablet, 30

9050H *Chem mart Amlodipine/Atorvastatin 5/20, CH* – **AMLODIPINE + ATORVASTATIN**, amlodipine 5 mg + atorvastatin 20 mg tablet, 30

9050H *Terry White Chemists Amlodipine/Atorvastatin 5/20, TW* – **AMLODIPINE + ATORVASTATIN**, amlodipine 5 mg + atorvastatin 20 mg tablet, 30

9051J *Chem mart Amlodipine/Atorvastatin 5/40, CH* – **AMLODIPINE + ATORVASTATIN**, amlodipine 5 mg + atorvastatin 40 mg tablet, 30

9051J *Terry White Chemists Amlodipine/Atorvastatin 5/40, TW* – **AMLODIPINE + ATORVASTATIN**, amlodipine 5 mg + atorvastatin 40 mg tablet, 30

9052K *Chem mart Amlodipine/Atorvastatin 5/80, CH* – **AMLODIPINE + ATORVASTATIN**, amlodipine 5 mg + atorvastatin 80 mg tablet, 30

9052K *Terry White Chemists Amlodipine/Atorvastatin 5/80, TW* – **AMLODIPINE + ATORVASTATIN**, amlodipine 5 mg + atorvastatin 80 mg tablet, 30

9053L *Chem mart Amlodipine/Atorvastatin 10/10, CH* – **AMLODIPINE + ATORVASTATIN**, amlodipine 10 mg + atorvastatin 10 mg tablet, 30

9053L *Terry White Chemists Amlodipine/Atorvastatin 10/10, TW* – **AMLODIPINE + ATORVASTATIN**, amlodipine 10 mg + atorvastatin 10 mg tablet, 30

9054M *Chem mart Amlodipine/Atorvastatin 10/20, CH* – **AMLODIPINE + ATORVASTATIN**, amlodipine 10 mg + atorvastatin 20 mg tablet, 30

9054M *Terry White Chemists Amlodipine/Atorvastatin 10/20, TW* – **AMLODIPINE + ATORVASTATIN**, amlodipine 10 mg + atorvastatin 20 mg tablet, 30

9055N *Chem mart Amlodipine/Atorvastatin 10/40, CH* – **AMLODIPINE + ATORVASTATIN**, amlodipine 10 mg + atorvastatin 40 mg tablet, 30

9055N *Terry White Chemists Amlodipine/Atorvastatin 10/40, TW* – **AMLODIPINE + ATORVASTATIN**, amlodipine 10 mg + atorvastatin 40 mg tablet, 30

9056P *Chem mart Amlodipine/Atorvastatin 10/80, CH* – **AMLODIPINE + ATORVASTATIN**, amlodipine 10 mg + atorvastatin 80 mg tablet, 30

9056P *Terry White Chemists Amlodipine/Atorvastatin 10/80, TW* – **AMLODIPINE + ATORVASTATIN**, amlodipine 10 mg + atorvastatin 80 mg tablet, 30

8361C *Capecitabine Sandoz, SZ* – **CAPECITABINE**, capecitabine 150 mg tablet, 60

8315P *Cefepime Sandoz, SZ* – **CEFEPIME**, CEFEPIME Powder for injection 1 g (as hydrochloride), 1

8316Q *Cefepime Sandoz, SZ* – **CEFEPIME**, CEFEPIME Powder for injection 2 g (as hydrochloride), 1

8405J *Irbesartan/HCTZ RBX 300/12.5, RA* – **IRBESARTAN + HYDROCHLOROTHIAZIDE**, irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30

2593L *Ferrum H, AS* – **IRON POLYMALTOSE**, iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules

2805P *Ferrum H, AS* – **IRON POLYMALTOSE**, iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules

3010K *Norfloxacin Sandoz, SZ* – **NORFLOXACIN**, norfloxacin 400 mg tablet, 14

8664B *Riluzole Winthrop, WA* – **RILUZOLE**, riluzole 50 mg tablet, 56

9391G *Chem mart Risedronate, CH* – **RISEDRONATE**, risedronate sodium 150 mg tablet, 1

9391G *Terry White Chemists Risedronate, TW* – **RISEDRONATE**, risedronate sodium 150 mg tablet, 1

2000G *Ventolin Nebules, GK* – **SALBUTAMOL**, salbutamol 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

8378Y *Astromide, FR* – **TEMOZOLOMIDE**, temozolomide 5 mg capsule, 5

8819E *Astromide, FR* – **TEMOZOLOMIDE**, temozolomide 5 mg capsule, 5

8379B *Astromide, FR* – **TEMOZOLOMIDE**, temozolomide 20 mg capsule, 5

8820F *Astromide, FR* – **TEMOZOLOMIDE**, temozolomide 20 mg capsule, 5

8380C *Astromide, FR* – **TEMOZOLOMIDE**, temozolomide 100 mg capsule, 5

8821G *Astromide, FR* – **TEMOZOLOMIDE**, temozolomide 100 mg capsule, 5

9361Q *Astromide, FR* – **TEMOZOLOMIDE**, temozolomide 140 mg capsule, 5

9362R *Astromide, FR* – **TEMOZOLOMIDE**, temozolomide 140 mg capsule, 5

10062N *Astromide, FR* – **TEMOZOLOMIDE**, temozolomide 180 mg capsule, 5

2438H *Astromide, FR* – **TEMOZOLOMIDE**, temozolomide 180 mg capsule, 5

8381D *Astromide, FR* – **TEMOZOLOMIDE**, temozolomide 250 mg capsule, 5

1279H *Tenopt, QA* – **TIMOLOL**, timolol 0.5% eye drops, 5 mL

5548B *Tenopt, QA* – **TIMOLOL**, timolol 0.5% eye drops, 5 mL

***Deletion – Equivalence Indicator***

1758M *Hospira Pty Limited, PF* – **CEFOTAXIME**, CEFOTAXIME Powder for injection 1 g, 10

1768C *Hospira Pty Limited, PF* – **CEFOTAXIME**, CEFOTAXIME Powder for injection 1 g, 10

11148R *Pregnyl, MK* – **HUMAN CHORIONIC GONADOTROPHIN**, human chorionic gonadotrophin 1500 units injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack

2593L *Ferrosig, SI* – **IRON POLYMALTOSE**, iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules

2805P *Ferrosig, SI* – **IRON POLYMALTOSE**, iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules

1279H *Timoptol, MF* – **TIMOLOL**, timolol 0.5% eye drops, 5 mL

5548B *Timoptol, MF* – **TIMOLOL**, timolol 0.5% eye drops, 5 mL

### *Deletion – Note*

1758M **CEFOTAXIME**, CEFOTAXIME Powder for injection 1 g, 10 *(Hospira Pty Limited)*

1768C **CEFOTAXIME**, CEFOTAXIME Powder for injection 1 g, 10 *(Hospira Pty Limited)*

11148R **HUMAN CHORIONIC GONADOTROPHIN**, human chorionic gonadotrophin 1500 units injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack *(Pregnyl)*

## Alterations

### *Alteration – Brand Name*

*From*

5190E *OxyNorm Liquid 5mg/5mL, MF* – **OXYCODONE**, oxycodone hydrochloride 1 mg/mL oral liquid, 250 mL

*To*

5190E *OxyNorm Liquid 1mg/mL, MF* – **OXYCODONE**, oxycodone hydrochloride 1 mg/mL oral liquid, 250 mL

*From*

8644Y *OxyNorm Liquid 5mg/5mL, MF* – **OXYCODONE**, oxycodone hydrochloride 1 mg/mL oral liquid, 250 mL

*To*

8644Y *OxyNorm Liquid 1mg/mL, MF* – **OXYCODONE**, oxycodone hydrochloride 1 mg/mL oral liquid, 250 mL

### *Alteration – Note*

9186L **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL syringes *(Humira)*

9187M **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges *(Humira)*

9188N **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes *(Humira)*

9189P **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes *(Humira)*

9190Q **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges *(Humira)*

9191R **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges *(Humira)*

8385H **OXYCODONE**, oxycodone hydrochloride 10 mg modified release tablet, 28 *(Novacodone, OxyContin, Oxycodone Sandoz)*

8386J **OXYCODONE**, oxycodone hydrochloride 20 mg modified release tablet, 28 *(Novacodone, OxyContin, Oxycodone Sandoz)*

8387K **OXYCODONE**, oxycodone hydrochloride 40 mg modified release tablet, 28 *(Novacodone, OxyContin, Oxycodone Sandoz)*

8388L **OXYCODONE**, oxycodone hydrochloride 80 mg modified release tablet, 28 *(Novacodone, OxyContin, Oxycodone Sandoz)*

1349B **VERTEPORFIN**, verteporfin 15 mg injection, 1 vial *(Visudyne)*

### *Alteration – Restriction*

10505X **AFLIBERCEPT**, aflibercept 4 mg/0.1 mL injection, 0.1 mL vial *(Eylea)*

2168D **AFLIBERCEPT**, aflibercept 4 mg/0.1 mL injection, 0.1 mL vial *(Eylea)*

1758M **CEFOTAXIME**, CEFOTAXIME Powder for injection 1 g, 10 *(Hospira Pty Limited)*

1768C **CEFOTAXIME**, CEFOTAXIME Powder for injection 1 g, 10 *(Hospira Pty Limited)*

10943Y **DEXAMETHASONE**, dexamethasone 700 microgram implant, 1 *(Ozurdex)*

10138N **RANIBIZUMAB**, ranibizumab 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe *(Lucentis)*

10373Y **RANIBIZUMAB**, ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial *(Lucentis)*

10374B **RANIBIZUMAB**, ranibizumab 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe *(Lucentis)*

1382R **RANIBIZUMAB**, ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial *(Lucentis)*

1349B **VERTEPORFIN**, verteporfin 15 mg injection, 1 vial *(Visudyne)*

11070P **VISMODEGIB**, vismodegib 150 mg capsule, 28 *(Erivedge)*

## Advance Notices

***1 November 2017***

***Deletion – Brand***

3116B *Cal-Sup, IA* – **CALCIUM**, CALCIUM Tablet (chewable) 500 mg (as carbonate), 60

1210Q *Ciprofloxacin-BW, GQ* – **CIPROFLOXACIN**, ciprofloxacin 750 mg tablet, 14

10889D *Gastro-Stop Loperamide, AS* – **LOPERAMIDE**, loperamide hydrochloride 2 mg capsule, 12

1571Q *Gastro-Stop Loperamide, AS* – **LOPERAMIDE**, loperamide hydrochloride 2 mg capsule, 12

1818Q *Methaccord, EA* – **METHOTREXATE**, METHOTREXATE Injection 50 mg in 2 mL, 1

***1 December 2017***

***Deletion – Brand***

10932J *Ridaura, GH* – **AURANOFIN**, auranofin 3 mg tablet, 100

8883M *Avanza, MK* – **MIRTAZAPINE**, mirtazapine 45 mg tablet, 30

8973G *Actonel EC Combi, UA* – **RISEDRONATE (&) CALCIUM CARBONATE**, RISEDRONATE SODIUM and CALCIUM CARBONATE Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1

***1 January 2018***

***Deletion – Brand***

1411G *add-ins, SB* – **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE**, AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE Sachets 18.2 g, 60, 1

8974H *Actonel EC Combi D, UA* – **RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL**, RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, 1

# Palliative Care

## Additions

***Addition – Brand***

5368M *APO-Ibuprofen 400, TX* – **IBUPROFEN**, ibuprofen 400 mg tablet, 30

5343F *APOHEALTH Osteo Relief Paracetamol 665 mg, TX* – **PARACETAMOL**, paracetamol 665 mg modified release tablet, 96

***Addition – Equivalence Indicator***

5368M *Brufen, GO* – **IBUPROFEN**, ibuprofen 400 mg tablet, 30

# Highly Specialised Drugs Program (Private Hospital)

## Additions

***Addition – Brand***

6100C *AZACITIDINE DR.REDDY'S, RI* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

6138C *AZACITIDINE DR.REDDY'S, RI* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

***Addition – Note***

11164N **USTEKINUMAB**, ustekinumab 130 mg/26 mL injection, 26 mL vial *(Stelara)*

## Deletions

***Deletion – Note***

11166Q **PEGVISOMANT**, pegvisomant 20 mg injection [1 vial] (&) inert substance diluent [1 x 1 mL syringe],vial], 1 pack *(Somavert)*

11167R **PEGVISOMANT**, pegvisomant 10 mg injection [30 vials] (&) inert substance diluent [30 x 1 mL syringes],vials], 1 pack *(Somavert)*

11172B **PEGVISOMANT**, pegvisomant 15 mg injection [30 vials] (&) inert substance diluent [30 x 1 mL syringes],vials], 1 pack *(Somavert)*

11174D **PEGVISOMANT**, pegvisomant 20 mg injection [30 vials] (&) inert substance diluent [30 x 1 mL syringes],vials], 1 pack *(Somavert)*

## Alterations

### *Alteration – Item Description*

*From*

11166Q **PEGVISOMANT**, pegvisomant 20 mg injection [1 vial] (&) inert substance diluent [1 x 1 mL vial], 1 pack *(Somavert)*

*To*

11166Q **PEGVISOMANT**, pegvisomant 20 mg injection [1 vial] (&) inert substance diluent [1 syringe], 1 pack *(Somavert)*

*From*

11167R **PEGVISOMANT**, pegvisomant 10 mg injection [30 vials] (&) inert substance diluent [30 x 1 mL vials], 1 pack *(Somavert)*

*To*

11167R **PEGVISOMANT**, pegvisomant 10 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack *(Somavert)*

*From*

11172B **PEGVISOMANT**, pegvisomant 15 mg injection [30 vials] (&) inert substance diluent [30 x 1 mL vials], 1 pack *(Somavert)*

*To*

11172B **PEGVISOMANT**, pegvisomant 15 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack *(Somavert)*

*From*

11174D **PEGVISOMANT**, pegvisomant 20 mg injection [30 vials] (&) inert substance diluent [30 x 1 mL vials], 1 pack *(Somavert)*

*To*

11174D **PEGVISOMANT**, pegvisomant 20 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack *(Somavert)*

### *Alteration – Note*

9613Y **INFLIXIMAB**, infliximab 100 mg injection, 1 vial *(Inflectra, Remicade, Renflexis)*

10415E **VEDOLIZUMAB**, vedolizumab 300 mg injection, 1 vial *(Entyvio)*

### *Alteration – Restriction*

11166Q **PEGVISOMANT**, pegvisomant 20 mg injection [1 vial] (&) inert substance diluent [1 x 1 mL syringe],vial], 1 pack *(Somavert)*

11167R **PEGVISOMANT**, pegvisomant 10 mg injection [30 vials] (&) inert substance diluent [30 x 1 mL syringes],vials], 1 pack *(Somavert)*

11172B **PEGVISOMANT**, pegvisomant 15 mg injection [30 vials] (&) inert substance diluent [30 x 1 mL syringes],vials], 1 pack *(Somavert)*

11174D **PEGVISOMANT**, pegvisomant 20 mg injection [30 vials] (&) inert substance diluent [30 x 1 mL syringes],vials], 1 pack *(Somavert)*

## Advance Notices

### *1 December 2017*

### *Deletion – Brand*

10235Q *Apomine, PF* – **APOMORPHINE**, apomorphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules

# Highly Specialised Drugs Program (Public Hospital)

## Additions

### *Addition – Brand*

9597D *AZACITIDINE DR.REDDY'S, RI* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

9598E *AZACITIDINE DR.REDDY'S, RI* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

### *Addition – Note*

11182M **USTEKINUMAB**, ustekinumab 130 mg/26 mL injection, 26 mL vial *(Stelara)*

## Deletions

### *Deletion – Note*

11173C **PEGVISOMANT**, pegvisomant 15 mg injection [30 vials] (&) inert substance diluent [30 x 1 mL syringes],vials], 1 pack *(Somavert)*

11177G **PEGVISOMANT**, pegvisomant 20 mg injection [1 vial] (&) inert substance diluent [1 x 1 mL syringe],vial], 1 pack *(Somavert)*

11179J **PEGVISOMANT**, pegvisomant 10 mg injection [30 vials] (&) inert substance diluent [30 x 1 mL syringes],vials], 1 pack *(Somavert)*

11181L **PEGVISOMANT**, pegvisomant 20 mg injection [30 vials] (&) inert substance diluent [30 x 1 mL syringes],vials], 1 pack *(Somavert)*

## Alterations

### *Alteration – Item Description*

*From*

11173C **PEGVISOMANT**, pegvisomant 15 mg injection [30 vials] (&) inert substance diluent [30 x 1 mL vials], 1 pack *(Somavert)*

*To*

11173C **PEGVISOMANT**, pegvisomant 15 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack *(Somavert)*

*From*

11177G **PEGVISOMANT**, pegvisomant 20 mg injection [1 vial] (&) inert substance diluent [1 x 1 mL vial], 1 pack *(Somavert)*

*To*

11177G **PEGVISOMANT**, pegvisomant 20 mg injection [1 vial] (&) inert substance diluent [1 syringe], 1 pack *(Somavert)*

*From*

11179J **PEGVISOMANT**, pegvisomant 10 mg injection [30 vials] (&) inert substance diluent [30 x 1 mL vials], 1 pack *(Somavert)*

*To*

11179J **PEGVISOMANT**, pegvisomant 10 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack *(Somavert)*

*From*

11181L **PEGVISOMANT**, pegvisomant 20 mg injection [30 vials] (&) inert substance diluent [30 x 1 mL vials], 1 pack *(Somavert)*

*To*

11181L **PEGVISOMANT**, pegvisomant 20 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack *(Somavert)*

### *Alteration – Note*

5754W **INFLIXIMAB**, infliximab 100 mg injection, 1 vial *(Inflectra, Remicade, Renflexis)*

10390W **VEDOLIZUMAB**, vedolizumab 300 mg injection, 1 vial *(Entyvio)*

### *Alteration – Restriction*

11173C **PEGVISOMANT**, pegvisomant 15 mg injection [30 vials] (&) inert substance diluent [30 x 1 mL syringes],vials], 1 pack *(Somavert)*

11177G **PEGVISOMANT**, pegvisomant 20 mg injection [1 vial] (&) inert substance diluent [1 x 1 mL syringe],vial], 1 pack *(Somavert)*

11179J **PEGVISOMANT**, pegvisomant 10 mg injection [30 vials] (&) inert substance diluent [30 x 1 mL syringes],vials], 1 pack *(Somavert)*

11181L **PEGVISOMANT**, pegvisomant 20 mg injection [30 vials] (&) inert substance diluent [30 x 1 mL syringes],vials], 1 pack *(Somavert)*

### Advance Notices
***1 December 2017***
***Deletion – Brand***

10227G *Apomine, PF* – **APOMORPHINE**, apomorphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules

## Highly Specialised Drugs Program (Community Access)

### Advance Notices
***1 December 2017***
***Deletion – Brand***

10352W *Foscavir, LM* – **FOSCARNET**, FOSCARNET SODIUM I.V. infusion 24 mg per mL, 250 mL bottle, 6

## Growth Hormone Program

### Deletions
***Deletion – Item***

10427T **SOMATROPIN**, somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge *(Omnitrope)*

10484T **SOMATROPIN**, somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge *(Omnitrope)*

6476W **SOMATROPIN**, somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge *(Omnitrope)*

## IVF Program

### Deletions
***Deletion – Item***

6178E **HUMAN CHORIONIC GONADOTROPHIN**, human chorionic gonadotrophin 1500 units injection [3 ampoules] (&) inert substance diluent [3 x 1 mL ampoules], 1 pack *(Pregnyl)*

6181H **HUMAN CHORIONIC GONADOTROPHIN**, human chorionic gonadotrophin 5000 units injection [1 ampoule] (&) inert substance diluent [1 mL ampoule], 1 pack *(Pregnyl)*

***Deletion – Equivalence Indicator***

11154C *Pregnyl, MK* – **HUMAN CHORIONIC GONADOTROPHIN**, human chorionic gonadotrophin 1500 units injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack

11156E *Pregnyl, MK* – **HUMAN CHORIONIC GONADOTROPHIN**, human chorionic gonadotrophin 5000 units injection [1 vial] (&) inert substance diluent [1 mL vial], 1 pack

***Deletion – Note***

11154C **HUMAN CHORIONIC GONADOTROPHIN**, human chorionic gonadotrophin 1500 units injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack *(Pregnyl)*

11156E **HUMAN CHORIONIC GONADOTROPHIN**, human chorionic gonadotrophin 5000 units injection [1 vial] (&) inert substance diluent [1 mL vial], 1 pack *(Pregnyl)*

## Repatriation Pharmaceutical Benefits

### Deletions
***Deletion – Item***

4170L **PARACETAMOL + CODEINE**, paracetamol 500 mg + codeine phosphate 15 mg tablet, 20 *(Prodeinextra)*

### Advance Notices
***1 November 2017***
***Deletion – Brand***

4094L *Cal-Sup, IA* – **CALCIUM**, CALCIUM Tablet (chewable) 500 mg (as carbonate), 60

4333C *Cal-Sup, IA* – **CALCIUM**, CALCIUM Tablet (chewable) 500 mg (as carbonate), 60

4171M *Codalgin, FM* – **PARACETAMOL + CODEINE**, paracetamol 500 mg + codeine phosphate 8 mg tablet, 50

# About the Schedule

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

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

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

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

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

## Symbols and Abbreviations Used in the Schedule

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

# Restricted Benefits

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

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

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

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

# Guidelines and General Statements

## General Statement for Lipid-Lowering Drugs

Use the following criteria to determine patient eligibility for subsidisation under the PBS for lipid modifying agents.

By writing a PBS prescription, the prescriber is certifying the patient satisfies the qualifying criteria set out below and the use is in accordance with the registered indications which differ between agents in this class - refer to the current Product Information for details. Note also that patients already established on a particular lipid-lowering drug, where use satisfies the PBS qualifying criteria, but is outside the registered indications for that drug, are not required to switch to another drug in the class to retain PBS eligibility.

Patients in very high risk categories (see below) may commence drug therapy with statins or fibrates immediately (ie simultaneously with an appropriate diet). For all other patients, dietary therapy should be trialled prior to initiation of drug therapy.

Dietary therapy should be continued concurrently with pharmacological therapy and should be reviewed on at least an annual basis.

Patients identified as being in one of the following very high risk categories may commence drug therapy with statins or fibrates at any cholesterol level:

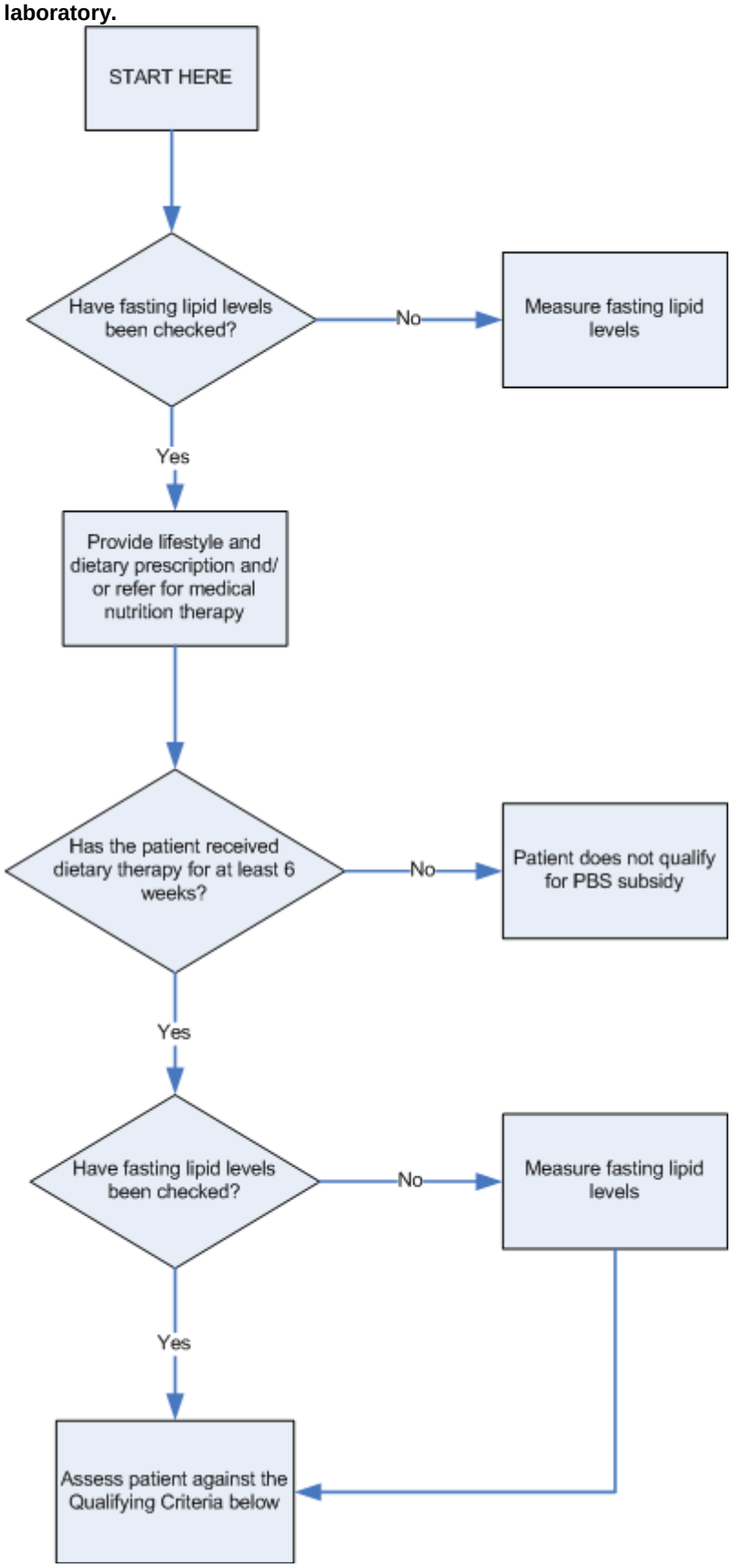
- coronary heart disease which has become symptomatic
- cerebrovascular disease which has become symptomatic
- peripheral vascular disease which has become symptomatic
- diabetes mellitus with microalbuminuria (defined as urinary albumin excretion rate of >20mcg/min or urinary albumin to creatinine ratio of > 2.5 for males, > 3.5 for females)
- diabetes mellitus in Aboriginal or Torres Strait Islander patients
- diabetes mellitus in patients aged 60 years or more
- family history of coronary heart disease which has become symptomatic before the age of 55 years in two or more first degree relatives
- family history of coronary heart disease which has become symptomatic before the age of 45 years in one or more first degree relatives

**POST-DIETARY QUALIFYING CRITERIA**

Dietary therapy should be continued concurrently with pharmacological therapy and should be reviewed on at least an annual basis.

| **PATIENT CATEGORY** | **LIPID LEVELS FOR PBS SUBSIDY** |
|---|---|
| Patients with diabetes mellitus not otherwise included | total cholesterol > 5.5 mmol/L |
| Aboriginal or Torres Strait Islander patients<br>Patients with hypertension | total cholesterol > 6.5 mmol/L **or**<br>total cholesterol > 5.5 mmol/L **and**<br>HDL cholesterol < 1 mmol/L |
| Patients with HDL cholesterol < 1 mmol/L | total cholesterol > 6.5 mmol/L |
| Patients with familial hypercholesterolaemia identified by:<br>• DNA mutation; or<br>• tendon xanthomas in the patient or their first or second degree relative<br><br>Patients with:<br>• family history of coronary heart disease which has become symptomatic before the age of 60 years in one or more first degree relatives; or<br>• family history of coronary heart disease which has become symptomatic before the age of 50 years in one or more second degree relatives | If aged 18 years or less at treatment initiation:<br>LDL cholesterol > 4 mmol/L<br><br>If aged more than 18 years at treatment initiation:<br>LDL cholesterol > 5 mmol/L **or**<br>total cholesterol > 6.5 mmol/L **or**<br>total cholesterol > 5.5 mmol/L **and**<br>HDL cholesterol < 1 mmol/L |
| Patients not eligible under the above:<br>• men aged 35 to 75 years<br>• post-menopausal women aged up to 75 years | total cholesterol > 7.5 mmol/L **or**<br>triglyceride > 4 mmol/L |
| Patients not otherwise included | total cholesterol > 9 mmol/L **or**<br>triglyceride > 8 mmol/L |

**If your patient is not identified as being in any of the above very high risk categories, then use the flow-chart and table below to determine whether your patient satisfies the following criteria for subsidisation under the PBS. Document how the patient meets each of these steps in the patient record. Lipid levels must be measured at an accredited laboratory.**



# General Statement for Drugs for the Treatment of Hepatitis C

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

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

**Population criteria:**
Patient must be aged 18 years or older.

**Treatment criteria:**
Must be treated by a medical practitioner or an authorised nurse practitioner[1] experienced in the treatment of chronic hepatitis C infection; or in consultation with a gastroenterologist, hepatologist or infectious diseases physician experienced in the treatment of chronic hepatitis C infection.

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

a. the hepatitis C virus genotype; and
b. the patient's cirrhotic status (non-cirrhotic or cirrhotic)

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

a. evidence of chronic hepatitis C infection (repeatedly antibody to hepatitis C virus (anti-HCV) positive and hepatitis C virus ribonucleic acid (HCV RNA) positive); and
b. evidence of the hepatitis C virus genotype

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

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

| | **TREATMENT NAÏVE** | **TREATMENT EXPERIENCED** |
|---|---|---|
| Genotype 1 | LEDIPASVIR + SOFOSBUVIR **[8 or 12 weeks]** [2]<br>**OR**<br>DACLATASVIR and SOFOSBUVIR **[12 weeks]**<br>**OR**<br>SOFOSBUVIR and PEG-IFN and RBV **[12 weeks]**<br>**OR**<br>PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR **[12 weeks]** [3]<br>**OR**<br>PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV **[12 weeks]** [4]<br>**OR**<br>GRAZOPREVIR + ELBASVIR **[12 weeks]**<br>**OR**<br>SOFOSBUVIR + VELPATASVIR **[12 weeks]** | LEDIPASVIR + SOFOSBUVIR **[12 weeks]**<br>**OR**<br>DACLATASVIR and SOFOSBUVIR **[12 or 24 weeks]**<br>**OR**<br>SOFOSBUVIR and PEG-IFN and RBV **[12 weeks]**<br>**OR**<br>PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR **[12 weeks]** [3]<br>**OR**<br>PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV **[12 weeks]** [4]<br>**OR**<br>GRAZOPREVIR + ELBASVIR **[12 weeks]**<br>**OR**<br>GRAZOPREVIR + ELBASVIR and RBV **[16 weeks]** [5]<br>**OR**<br>SOFOSBUVIR + VELPATASVIR **[12 weeks]** |
| Genotype 2 | SOFOSBUVIR and RBV **[12 weeks]**<br>**OR**<br>SOFOSBUVIR + VELPATASVIR **[12 weeks]** | SOFOSBUVIR and RBV **[12 weeks]**<br>**OR**<br>SOFOSBUVIR + VELPATASVIR **[12 weeks]** |
| Genotype 3 | DACLATASVIR and SOFOSBUVIR **[12 weeks]**<br>**OR**<br>SOFOSBUVIR and RBV **[24 weeks]**<br>**OR**<br>SOFOSBUVIR and PEG-IFN and RBV **[12 weeks]**<br>**OR**<br>SOFOSBUVIR + VELPATASVIR **[12 weeks]** | DACLATASVIR and SOFOSBUVIR **[12 weeks]**<br>**OR**<br>SOFOSBUVIR and RBV **[24 weeks]**<br>**OR**<br>SOFOSBUVIR and PEG-IFN and RBV **[12 weeks]**<br>**OR**<br>SOFOSBUVIR + VELPATASVIR **[12 weeks]** |
| Genotype 4 | SOFOSBUVIR and PEG-IFN and RBV **[12 weeks]**<br>**OR**<br>GRAZOPREVIR + ELBASVIR **[12 weeks]**<br>**OR**<br>SOFOSBUVIR + VELPATASVIR **[12 weeks]** | SOFOSBUVIR and PEG-IFN and RBV **[12 weeks]**<br>**OR**<br>GRAZOPREVIR + ELBASVIR **[12 weeks]**<br>**OR**<br>GRAZOPREVIR + ELBASVIR and RBV **[16 weeks]** [5]<br>**OR**<br>SOFOSBUVIR + VELPATASVIR **[12 weeks]** |
| Genotype 5 & 6 | SOFOSBUVIR and PEG-IFN and RBV **[12 weeks]**<br>**OR**<br>SOFOSBUVIR + VELPATASVIR **[12 weeks]** | SOFOSBUVIR and PEG-IFN and RBV **[12 weeks]**<br>**OR**<br>SOFOSBUVIR + VELPATASVIR **[12 weeks]** |

**KEY**
PEG-IFN - peginterferon alfa-2a
RBV - ribavirin

[1] Medicines for the treatment of hepatitis C are listed for prescribing by authorised nurse practitioners under the General Schedule only. Medicines for the treatment of hepatitis C are not listed for prescribing by authorised nurse practitioners under the S100 Highly Specialised Drugs Program.

[2] [LEDIPASVIR + SOFOSBUVIR] for treatment-naïve, non-cirrhotic patients:
- consider treatment for 8 weeks where pre-treatment HCV RNA is less than 6 million IU/mL;
- otherwise treatment for 12 weeks where pre-treatment HCV RNA is 6 million IU/mL or greater.

[3] [PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR] for treatment-naïve and treatment experienced, non-cirrhotic patients, treatment for 12 weeks in patients with genotype 1b HCV.

[4] [PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV] for treatment-naïve and treatment experienced, non-cirrhotic patients, treatment for 12 weeks in patients with genotype 1a HCV.

[5] [GRAZOPREVIR + ELBASVIR and RBV] for treatment-experienced, non-cirrhotic and cirrhotic patients, treatment for 16 weeks in patients with genotype 1a or 4 HCV who have experienced on-treatment virologic failure to prior treatment.

## *HEPATITIS C – CIRRHOTIC PATIENTS*

| | TREATMENT NAÏVE | TREATMENT EXPERIENCED |
|---|---|---|
| Genotype 1 | LEDIPASVIR + SOFOSBUVIR **[12 weeks]**<br>**OR**<br>DACLATASVIR and SOFOSBUVIR and RBV **[12 weeks]**<br>**OR**<br>DACLATASVIR and SOFOSBUVIR **[24 weeks]**<br>**OR**<br>SOFOSBUVIR and PEG-IFN and RBV **[12 weeks]**<br>**OR**<br>PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV **[12 weeks]**<br>**OR**<br>GRAZOPREVIR + ELBASVIR **[12 weeks]**<br>**OR**<br>SOFOSBUVIR + VELPATASVIR **[12 weeks]** [6] | LEDIPASVIR + SOFOSBUVIR **[24 weeks]**<br>**OR**<br>DACLATASVIR and SOFOSBUVIR **[24 weeks]**<br>**OR**<br>DACLATASVIR and SOFOSBUVIR and RBV **[12 weeks]**<br>**OR**<br>SOFOSBUVIR and PEG-IFN and RBV **[12 weeks]**<br>**OR**<br>PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV **[12 or 24 weeks]** [7]<br>**OR**<br>GRAZOPREVIR + ELBASVIR **[12 weeks]**<br>**OR**<br>GRAZOPREVIR + ELBASVIR and RBV **[16 weeks]** [5]<br>**OR**<br>SOFOSBUVIR + VELPATASVIR **[12 weeks]** [6] |
| Genotype 2 | SOFOSBUVIR and RBV **[12 weeks]**<br>**OR**<br>SOFOSBUVIR + VELPATASVIR **[12 weeks]** [6] | SOFOSBUVIR and RBV **[12 weeks]**<br>**OR**<br>SOFOSBUVIR + VELPATASVIR **[12 weeks]** [6] |
| Genotype 3 | SOFOSBUVIR and RBV **[24 weeks]**<br>**OR**<br>DACLATASVIR and SOFOSBUVIR **[24 weeks]**<br>**OR**<br>SOFOSBUVIR and PEG-IFN and RBV **[12 weeks]**<br>**OR**<br>DACLATASVIR and SOFOSBUVIR and RBV **[12 or 24 weeks]** [8]<br>**OR**<br>SOFOSBUVIR + VELPATASVIR **[12 weeks]** [6,9] | DACLATASVIR and SOFOSBUVIR **[24 weeks]**<br>**OR**<br>SOFOSBUVIR and RBV **[24 weeks]**<br>**OR**<br>SOFOSBUVIR and PEG-IFN and RBV **[12 weeks]**<br>**OR**<br>DACLATASVIR and SOFOSBUVIR and RBV **[12 or 24 weeks]** [8]<br>**OR**<br>SOFOSBUVIR + VELPATASVIR **[12 weeks]** [6,9] |
| Genotype 4 | SOFOSBUVIR and PEG-IFN and RBV **[12 weeks]**<br>**OR**<br>GRAZOPREVIR + ELBASVIR **[12 weeks]**<br>**OR**<br>SOFOSBUVIR + VELPATASVIR **[12 weeks]** [6] | SOFOSBUVIR and PEG-IFN and RBV **[12 weeks]**<br>**OR**<br>GRAZOPREVIR + ELBASVIR **[12 weeks]**<br>**OR**<br>GRAZOPREVIR + ELBASVIR and RBV **[16 weeks]** [5]<br>**OR**<br>SOFOSBUVIR + VELPATASVIR **[12 weeks]** [6] |
| Genotype 5 & 6 | SOFOSBUVIR and PEG-IFN and RBV **[12 weeks]**<br>**OR**<br>SOFOSBUVIR + VELPATASVIR **[12 weeks]** [6] | SOFOSBUVIR and PEG-IFN and RBV **[12 weeks]**<br>**OR**<br>SOFOSBUVIR + VELPATASVIR [**12 weeks]** [6] |

**KEY**

PEG-IFN - peginterferon alfa-2a
RBV – ribavirin

[6] [SOFOSBUVIR + VELPATASVIR] for patients with decompensated cirrhosis:

- use in combination with ribavirin.

[7] [PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV] for treatment-experienced, cirrhotic patients:

- consider treatment for 12 weeks in patients with genotype 1a HCV (except prior null responders to PEG-IFN and RBV) and genotype 1b HCV; or
- consider treatment for 24 weeks in patients with genotype 1a HCV who have had a previous null response to PEG-IFN and RBV.

[8] [DACLATASVIR and SOFOSBUVIR and RBV] for cirrhotic patients consider a 24 week regimen of where clinically appropriate.

[9] [SOFOSBUVIR + VELPATASVIR] for patients with genotype 3 infection with compensated cirrhosis:

- consider addition of ribavirin.

# Pharmaceutical Benefits Schedules

# Prescriber Bag

## ▪ ADRENALINE

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

| 3451P | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| NP | 1 | 22.58 | Link Medical Products Pty Ltd [LM] |

## ▪ ATROPINE SULFATE

**ATROPINE Injection 600 micrograms in 1 mL, 10**

| 3453R | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| NP | 1 | 22.76 | Pfizer Australia Pty Ltd [PF] |

## ▪ BENZATROPINE

**benzatropine mesilate 2 mg/2 mL injection, 10 x 2 mL vials**

| 10016E | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| NP | 1 | 263.28 | Benztropine Omega [FK] |

**OR**

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

| 3457Y | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| NP | 1 | 95.01 | Cogentin [FK] |

## ▪ BENZYLPENICILLIN

**benzylpenicillin 600 mg injection, 1 vial**

| 3486L | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| NP | 5 | *36.25 | BenPen [CS] |

**OR**

## ▪ PROCAINE PENICILLIN

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

| 3485K | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| NP | 1 | 85.18 | Cilicaine [QA] |

## ▪ BENZYLPENICILLIN

**benzylpenicillin 3 g injection, 1 vial**

| 3487M | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| NP | 1 | 19.78 | BenPen [CS] |

## ▪ CHLORPROMAZINE

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

| 3455W | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| NP | 1 | 22.70 | Largactil [SW] |

**OR**

## ▪ HALOPERIDOL

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

| 3456X | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| NP | 1 | 24.20 | Serenace [QA] |

## ▪ CLONAZEPAM

**clonazepam 2.5 mg/mL oral liquid, 10 mL**

| 3478C | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| NP | ‡1 | 14.84 | Rivotril [RO] |

## ▪ DEXAMETHASONE SODIUM PHOSPHATE

**DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 4 mg dexamethasone phosphate in 1 mL, 5**

| 3472R | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|
| NP | 1 | 16.36 | [a] Dexamethasone Mylan [AF] | [a] Hospira Pty Limited [PF] |

**OR**

## ▪ HYDROCORTISONE SODIUM SUCCINATE

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

| 3470P | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| NP | 2 | *20.89 | Solu-Cortef [PF] |

**OR**

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

| 3471Q | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| NP | 1 | 19.85 | Solu-Cortef [PF] |

## ▪ DIAZEPAM

**diazepam 10 mg/2 mL injection, 5 x 2 mL ampoules**

| 3458B | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| NP | 1 | 17.11 | Hospira Pty Limited [PF] |

## ▪ DIPHTHERIA TOXOID + TETANUS TOXOID

**diphtheria toxoid 2 Lf/0.5 mL + tetanus toxoid 2 Lf/0.5 mL injection, 10 x 0.5 mL vials**

| 10244E | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| NP | 1 | 136.39 | MassBiologics tetanus and diphtheria toxoids adsorbed [CS] |

**OR**

## ▪ DIPHTHERIA TOXOID + TETANUS TOXOID

**diphtheria toxoid 2 international units/0.5 mL + tetanus toxoid 20 international units/0.5 mL injection, 5 x 0.5 mL syringes**

| 3463G | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| NP | 2 | *130.13 | ADT Booster [CS] |

## ▪ FRUSEMIDE

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

| 3466K | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|
| NP | 1 | 13.24 | [a] Frusemide-Claris [AE]<br>[a] Lasix [SW] | [a] Frusemide Sandoz [SZ] |

## ▪ GLUCAGON HYDROCHLORIDE

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

| 3467L | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| NP | 1 | 50.97 | GlucaGen Hypokit [NO] |

## ▪ GLYCERYL TRINITRATE

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

| 3475X | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| NP | ‡1 | 23.01 | Nitrolingual Pumpspray [SW] |

## ▪ HYOSCINE BUTYLBROMIDE

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

| 3473T | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| NP | 1 | 25.79 | Buscopan [VZ] |

## ▪ LIGNOCAINE

**lignocaine hydrochloride anhydrous 1% (50 mg/5 mL) injection, 5 x 5 mL ampoules**

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 10209H NP | 1 | 36.63 | Pfizer Australia Pty Ltd [PF] |

## ▪ METHOXYFLURANE

**methoxyflurane 999.9 mg/g inhalation solution, 3 mL**

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 3489P | 1 | 43.26 | Penthrox [DV] |

## ▪ METOCLOPRAMIDE

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

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 3476Y NP | 1 | 16.80 | Maxolon [IA] |

**OR**

## ▪ PROCHLORPERAZINE

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

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 3477B NP | 1 | 20.77 | Stemetil [SW] |

## ▪ MIDAZOLAM

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

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 10178Q NP | 1 | 39.05 | Pfizer Australia Pty Ltd [PF] |

## ▪ MORPHINE

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

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 3480E NP | 1 | 23.92 | Hospira Pty Limited [PF] |

**OR**

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

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 10868B NP | 1 | 23.78 | Morphine Juno [JU] |

**OR**

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

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 10862Q NP | 1 | 20.42 | Morphine Juno [JU] |

**OR**

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

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 3479D NP | 1 | 21.82 | Hospira Pty Limited [PF] |

## ▪ NALOXONE

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

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|
| 10786Q NP | 2 | *153.87 | [a] Naloxone Hydrochloride (DBL) [PF] | [a] Naloxone Juno [JU] |

## ▪ OXYTOCIN

**oxytocin 10 units/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 10251M | 1 | 61.09 | Oxytocin Sandoz [SZ] |

## ▪ PHYTOMENADIONE

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

| 10213M | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| | 1 | 24.58 | Konakion MM [RO] |

## ▪ PROMETHAZINE

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

| 3488N | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| NP | 2 | *38.67 | Hospira Pty Limited [PF] |

## ▪ SALBUTAMOL

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

| 3495Y | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| NP | ‡1 | 14.80 | [a] Asmol CFC-free [AL] |
| | | 16.07 | [a] Ventolin CFC-free [GK] |

**OR**

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

| 11125M | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| NP | ‡1 | 14.10 | Ventolin Nebules [GK] |

**OR**

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

| 3496B | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|
| NP | ‡1 | 15.09 | [a] APO-Salbutamol [TX] | [a] Butamol 2.5 [QA] |
| | | | [a] Salbutamol Actavis [EA] | [a] Salbutamol Sandoz [SZ] |
| | | 15.34 | [a] Asmol 2.5 uni-dose [AF] | |

## ▪ SALBUTAMOL

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

| 11088N | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| NP | ‡1 | 14.23 | Ventolin Nebules [GK] |

**OR**

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

| 3497C | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|
| NP | ‡1 | 15.30 | [a] APO-Salbutamol [TX] | [a] Butamol 5 [QA] |
| | | | [a] Salbutamol Actavis [EA] | [a] Salbutamol Sandoz [SZ] |
| | | 15.55 | [a] Asmol 5 uni-dose [AF] | |

## ▪ TRAMADOL

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

| 3484J | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|
| NP | 1 | 13.94 | [a] Tramadol ACT [EA] | [a] Tramadol Sandoz [SZ] |
| | | | [a] Tramal 100 [CS] | |

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# ALIMENTARY TRACT AND METABOLISM

## STOMATOLOGICAL PREPARATIONS

### STOMATOLOGICAL PREPARATIONS

*Antiinfectives and antiseptics for local oral treatment*

#### AMPHOTERICIN B

**amphotericin B 10 mg lozenge, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2931G NP | 1 | 1 | .. | 15.72 | 16.93 | Fungilin [QA] |

**amphotericin B 10 mg lozenge, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3306B DP | 1 | .. | .. | 15.72 | 16.93 | Fungilin [QA] |

*Other agents for local oral treatment*

#### BENZYDAMINE

**Restricted benefit**

Mucositis

**Clinical criteria:**

- The condition must be radiation induced.

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1121B NP | ‡1 | 1 | .. | 24.18 | 25.39 | Difflam [IA] |

#### BENZYDAMINE

**Restricted benefit**

Mucositis

**Clinical criteria:**

- The condition must be radiation induced.

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5032W DP | ‡1 | .. | .. | 24.18 | 25.39 | Difflam [IA] |

## DRUGS FOR ACID RELATED DISORDERS

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

*H2-receptor antagonists*

#### CIMETIDINE

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

**cimetidine 400 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1158Y NP | 1 | 5 | .. | 20.09 | 21.30 | Magicul 400 [AF] |

#### FAMOTIDINE

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

**famotidine 40 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2488Y NP | 1 | 5 | .. | 14.94 | 16.15 | [a] Ausfam 40 [RW]<br>[a] Famotidine Sandoz [SZ]<br>[a] Pepzan [ED] | [a] Famotidine AN [EA]<br>[a] GenRx Famotidine [GX] |

**famotidine 20 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2487X NP | 1 | 5 | .. | 14.94 | 16.15 | [a] Ausfam 20 [RW]<br>[a] Famotidine Sandoz [SZ]<br>[a] Pepzan [ED] | [a] Famotidine AN [EA]<br>[a] GenRx Famotidine [GX] |

## ▪ NIZATIDINE

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

**nizatidine 300 mg capsule, 30**

| 1504E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 21.53 | 22.74 | [a] Tacidine [AF] |
| | | | [B]2.03 | 23.56 | 22.74 | [a] Nizac [RF] |
| | | | [B]6.61 | 28.14 | 22.74 | [a] Tazac [RW] |

**nizatidine 150 mg capsule, 60**

| 1505F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 21.53 | 22.74 | [a] Tacidine [AF] |
| | | | [B]2.03 | 23.56 | 22.74 | [a] Nizac [RF] |
| | | | [B]6.61 | 28.14 | 22.74 | [a] Tazac [RW] |

## ▪ RANITIDINE

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

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

| 8162N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *26.83 | 28.04 | Zantac Syrup [AS] |

**ranitidine 300 mg tablet, 30**

| 1977C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.55 | 15.76 | [a] APO-Ranitidine [TX]<br>[a] Chem mart Ranitidine [CH]<br>[a] Ranitidine GH [GQ]<br>[a] Terry White Chemists Ranitidine [TW] | [a] Ausran [RW]<br>[a] Rani 2 [AF]<br>[a] Ranitidine Sandoz [SZ] |
| | | | [B]1.68 | 16.23 | 15.76 | [a] Zantac [AS] | |

## ▪ RANITIDINE

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

**Note** Pharmaceutical benefits that have the form ranitidine tablet 150 mg (as hydrochloride) and pharmaceutical benefits that have the form ranitidine tablet, effervescent, 150 mg (as hydrochloride) are equivalent for the purposes of substitution.

**ranitidine 150 mg effervescent tablet, 30**

| 1937Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | [B]1.16 | *16.15 | 16.20 | [a] Zantac [AS] |

**ranitidine 150 mg tablet, 60**

| 1978D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 5 | .. | 14.55 | 15.76 | [a] APO-Ranitidine [TX]<br>[a] Chem mart Ranitidine [CH]<br>[a] Ranitidine AN [EA]<br>[a] Ranitidine Sandoz [SZ]<br>[a] Ulcaid [RA] | [a] Ausran [RW]<br>[a] Rani 2 [AF]<br>[a] Ranitidine GH [GQ]<br>[a] Terry White Chemists Ranitidine [TW] |
| | | | [B]1.68 | 16.23 | 15.76 | [a] Zantac [AS] | |

*Proton pump inhibitors*

## ▪ ESOMEPRAZOLE

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

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

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

**Restricted benefit**

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The treatment must be for the healing of gastro-oesophageal reflux disease.

**esomeprazole 40 mg capsule, 30**

| 10330Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 27.76 | 28.97 | [a] Esomeprazole ACTAVIS [EA] | [a] Noxicid Caps [AL] |

**esomeprazole 40 mg enteric tablet, 30**

8601Q NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 27.76 | 28.97 | [a] Esomeprazole AN [EA]<br>[a] Esomeprazole GH [GQ]<br>[a] Esomeprazole RBX [RA]<br>[a] Nexazole [RW]<br>[a] Nexole [RF] | [a] Esomeprazole Apotex [TX]<br>[a] Esomeprazole GxP [AF]<br>[a] Esomeprazole Sandoz [SZ]<br>[a] Nexium [AP] |

## ▪ ESOMEPRAZOLE

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

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

**Authority required**
Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

**Authority required**
Scleroderma oesophagus

**esomeprazole 40 mg capsule, 30**

10331R NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 27.76 | 28.97 | [a] Esomeprazole ACTAVIS [EA] | [a] Noxicid Caps [AL] |

**esomeprazole 40 mg enteric tablet, 30**

3401B NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 27.76 | 28.97 | [a] Esomeprazole AN [EA]<br>[a] Esomeprazole GH [GQ]<br>[a] Esomeprazole RBX [RA]<br>[a] Nexazole [RW]<br>[a] Nexole [RF] | [a] Esomeprazole Apotex [TX]<br>[a] Esomeprazole GxP [AF]<br>[a] Esomeprazole Sandoz [SZ]<br>[a] Nexium [AP] |

## ▪ ESOMEPRAZOLE

**Note Helicobacter pylori** eradication therapy should be considered.

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

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

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

**Restricted benefit**
Gastric ulcer
Treatment Phase: Initial treatment

**esomeprazole 20 mg capsule, 30**

10295W NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 20.92 | 22.13 | [a] Esomeprazole ACTAVIS [EA] | [a] Noxicid Caps [AL] |

**esomeprazole 20 mg enteric tablet, 30**

8886Q NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 20.92 | 22.13 | [a] Esomeprazole AN [EA]<br>[a] Esomeprazole GH [GQ]<br>[a] Esomeprazole RBX [RA]<br>[a] Nexazole [RW]<br>[a] Nexole [RF] | [a] Esomeprazole Apotex [TX]<br>[a] Esomeprazole GxP [AF]<br>[a] Esomeprazole Sandoz [SZ]<br>[a] Nexium [AP] |

## ▪ ESOMEPRAZOLE

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

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

**Restricted benefit**
Gastro-oesophageal reflux disease

**Clinical criteria:**

- The treatment must be maintenance therapy, **AND**
- The condition must be healed.

**Restricted benefit**
Scleroderma oesophagus

**Restricted benefit**
Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

**esomeprazole 20 mg capsule, 30**

| 10343J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 20.92 | 22.13 | [a] Esomeprazole ACTAVIS [EA] | [a] Noxicid Caps [AL] |

**esomeprazole 20 mg enteric tablet, 30**

| 8600P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 20.92 | 22.13 | [a] Esomeprazole AN [EA]<br>[a] Esomeprazole GH [GQ]<br>[a] Esomeprazole RBX [RA]<br>[a] Nexazole [RW]<br>[a] Nexole [RF] | [a] Esomeprazole Apotex [TX]<br>[a] Esomeprazole GxP [AF]<br>[a] Esomeprazole Sandoz [SZ]<br>[a] Nexium [AP] |

## ▪ LANSOPRAZOLE

**Restricted benefit**

Gastro-oesophageal reflux disease

**Restricted benefit**

Scleroderma oesophagus

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

| 9331D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.23 | 15.44 | [a] APO-Lansoprazole ODT [TX]<br>[a] Zopral ODT [AF] | [a] Lansoprazole ODT GH [GQ] |
| | | | [B]3.98 | 18.21 | 15.44 | [a] Zoton FasTabs [PF] | |

**lansoprazole 15 mg enteric capsule, 30**

| 8198L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.46 | 15.67 | Zopral [AF] |

## ▪ LANSOPRAZOLE

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

**Restricted benefit**

Gastro-oesophageal reflux disease

**Restricted benefit**

Scleroderma oesophagus

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

| 9478W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.72 | 17.93 | [a] APO-Lansoprazole ODT [TX]<br>[a] Zopral ODT [AF] | [a] Lansoprazole ODT GH [GQ] |
| | | | [B]3.99 | 20.71 | 17.93 | [a] Zoton FasTabs [PF] | |

**lansoprazole 30 mg enteric capsule, 28**

| 2241Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.72 | 17.93 | [a] APO-Lansoprazole [TX]<br>[a] Zopral [AF] | [a] Lanzopran [RA] |

## ▪ LANSOPRAZOLE

**Note Helicobacter pylori** eradication therapy should be considered.

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

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

**Restricted benefit**

Peptic ulcer

Treatment Phase: Initial treatment

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

| 9477T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 16.72 | 17.93 | [a] APO-Lansoprazole ODT [TX]<br>[a] Zopral ODT [AF] | [a] Lansoprazole ODT GH [GQ] |
| | | | [B]3.99 | 20.71 | 17.93 | [a] Zoton FasTabs [PF] | |

**lansoprazole 30 mg enteric capsule, 28**

| 2240X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 16.72 | 17.93 | [a] APO-Lansoprazole [TX]<br>[a] Zopral [AF] | [a] Lanzopran [RA] |

## ▪ OMEPRAZOLE

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

**omeprazole 10 mg enteric tablet, 30**

8332M NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 14.71 | 15.92 | Losec Tablets [AP] |

## ▪ OMEPRAZOLE

**Note Helicobacter pylori** eradication therapy should be considered.
**Note** Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.
**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**
Peptic ulcer
Treatment Phase: Initial treatment

**omeprazole 20 mg enteric tablet, 30**

8331L NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 15.52 | 16.73 | [a] APO-Omeprazole [TX]<br>[a] Meprazol [SZ]<br>[a] Omeprazole generichealth [GQ]<br>[a] Terry White Chemists Omeprazole [TW] | [a] Chem mart Omeprazole [CH]<br>[a] Omeprazole AN [EA]<br>[a] Ozmep [ZP] |

**omeprazole 20 mg enteric tablet, 30**

9109K NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 15.52 | 16.73 | [a] Acimax Tablets [AL]<br>[a] Omeprazole Sandoz [SZ] | [a] Omepral [ZA] |
| | | [B]3.06 | 18.58 | 16.73 | [a] Losec Tablets [AP] | |

**omeprazole 20 mg capsule, 30**

1326T NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 15.52 | 16.73 | [a] APO-Omeprazole [TX]<br>[a] Omeprazole Sandoz [HX]<br>[a] Pharmacor Omeprazole 20 [CR] | [a] Maxor [AF]<br>[a] Pemzo [RW]<br>[a] Probitor [SZ] |

## ▪ OMEPRAZOLE

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

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

**omeprazole 20 mg enteric tablet, 30**

8333N NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 15.52 | 16.73 | [a] APO-Omeprazole [TX]<br>[a] Meprazol [SZ]<br>[a] Omeprazole generichealth [GQ]<br>[a] Terry White Chemists Omeprazole [TW] | [a] Chem mart Omeprazole [CH]<br>[a] Omeprazole AN [EA]<br>[a] Ozmep [ZP] |

**omeprazole 20 mg enteric tablet, 30**

9110L NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 15.52 | 16.73 | [a] Acimax Tablets [AL]<br>[a] Omeprazole Sandoz [SZ] | [a] Omepral [ZA] |
| | | [B]3.06 | 18.58 | 16.73 | [a] Losec Tablets [AP] | |

**omeprazole 20 mg capsule, 30**

| 1327W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.52 | 16.73 | [a] APO-Omeprazole [TX]<br>[a] Omeprazole Sandoz [HX]<br>[a] Pharmacor Omeprazole 20 [CR] | [a] Maxor [AF]<br>[a] Pemzo [RW]<br>[a] Probitor [SZ] |

## ▪ PANTOPRAZOLE

**Note Helicobacter pylori** eradication therapy should be considered.
**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**
Peptic ulcer
Treatment Phase: Initial treatment

**pantoprazole 40 mg enteric tablet, 30**

| 8007K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 13.64 | 14.85 | [a] APO-Pantoprazole [TX]<br>[a] I-Pantoprazole [CR]<br>[a] Panthron [ER]<br>[a] Pantofast 40 [RZ]<br>[a] Pantoprazole AN [EA]<br>[a] Pantoprazole Sandoz [SZ]<br>[a] Somac [NQ]<br>[a] Topra 40 [DO] | [a] APOTEX-Pantoprazole [GX]<br>[a] Ozpan [RA]<br>[a] Panto [TK]<br>[a] Pantoprazole Actavis [ED]<br>[a] Pantoprazole GH [GQ]<br>[a] Salpraz [AF]<br>[a] Sozol [RW] |

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

| 9423Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 32.21 | 33.42 | Somac [NQ] |

## ▪ PANTOPRAZOLE

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

**pantoprazole 40 mg enteric tablet, 30**

| 8008L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 13.64 | 14.85 | [a] APO-Pantoprazole [TX]<br>[a] I-Pantoprazole [CR]<br>[a] Panthron [ER]<br>[a] Pantofast 40 [RZ]<br>[a] Pantoprazole AN [EA]<br>[a] Pantoprazole Sandoz [SZ]<br>[a] Somac [NQ]<br>[a] Topra 40 [DO] | [a] APOTEX-Pantoprazole [GX]<br>[a] Ozpan [RA]<br>[a] Panto [TK]<br>[a] Pantoprazole Actavis [ED]<br>[a] Pantoprazole GH [GQ]<br>[a] Salpraz [AF]<br>[a] Sozol [RW] |

**pantoprazole 20 mg enteric tablet, 30**

| 8399C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 12.34 | 13.55 | [a] APO-Pantoprazole [TX]<br>[a] Ozpan [RA]<br>[a] Panto [TK]<br>[a] Pantoprazole AN [EA]<br>[a] Pantoprazole Sandoz [SZ]<br>[a] Somac [NQ] | [a] APOTEX-Pantoprazole [GX]<br>[a] Panthron [ER]<br>[a] Pantofast 20 [RZ]<br>[a] Pantoprazole GH [GQ]<br>[a] Salpraz [AF]<br>[a] Sozol [RW] |

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

| 9424B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 32.21 | 33.42 | Somac [NQ] |

## ▪ RABEPRAZOLE

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

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

| 8507R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.13 | 15.34 | [a] APO-Rabeprazole [TX] | [a] Parbezol [RW] |
| | | | | | | [a] Parzol 10 [ZP] | [a] Rabeprazole AN [EA] |
| | | | | | | [a] Rabeprazole-DRLA [RZ] | [a] Rabeprazole generichealth [GQ] |
| | | | | | | [a] Rabeprazole Sandoz [SZ] | [a] Razit 10 [DO] |
| | | | [B]3.95 | 18.08 | 15.34 | [a] Pariet [JC] | |

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

| 8508T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.13 | 15.34 | [a] APO-Rabeprazole [TX] | [a] Chem mart Rabeprazole [CH] |
| | | | | | | [a] Parbezol [RW] | [a] Parzol 20 [ZP] |
| | | | | | | [a] Rabeprazole Actavis 20 [ED] | [a] Rabeprazole AN [EA] |
| | | | | | | [a] Rabeprazole-DRLA [RZ] | [a] Rabeprazole generichealth [GQ] |
| | | | | | | [a] Rabeprazole Sandoz [SZ] | [a] Rabeprazole SUN [RN] |
| | | | | | | [a] Razit 20 [DO] | [a] Terry White Chemists Rabeprazole [TW] |
| | | | | | | [a] Zabep [AL] | |
| | | | [B]3.95 | 18.08 | 15.34 | [a] Pariet [JC] | |

## ▪ RABEPRAZOLE

**Note Helicobacter pylori** eradication therapy should be considered.

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

**Restricted benefit**

Peptic ulcer

Treatment Phase: Initial treatment

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

| 8509W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 14.13 | 15.34 | [a] APO-Rabeprazole [TX] | [a] Chem mart Rabeprazole [CH] |
| | | | | | | [a] Parbezol [RW] | [a] Parzol 20 [ZP] |
| | | | | | | [a] Rabeprazole Actavis 20 [ED] | [a] Rabeprazole AN [EA] |
| | | | | | | [a] Rabeprazole-DRLA [RZ] | [a] Rabeprazole generichealth [GQ] |
| | | | | | | [a] Rabeprazole Sandoz [SZ] | [a] Rabeprazole SUN [RN] |
| | | | | | | [a] Razit 20 [DO] | [a] Terry White Chemists Rabeprazole [TW] |
| | | | | | | [a] Zabep [AL] | |
| | | | [B]3.95 | 18.08 | 15.34 | [a] Pariet [JC] | |

*Combinations for eradication of Helicobacter pylori*

## ▪ ESOMEPRAZOLE (&) CLARITHROMYCIN (&) AMOXYCILLIN

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

**Restricted benefit**

Eradication of Helicobacter pylori

**Clinical criteria:**

- The condition must be associated with peptic ulcer disease.

**esomeprazole 20 mg tablet: enteric [14 tablets] (&) clarithromycin 500 mg tablet [14 tablets] (&) amoxycillin 500 mg capsule [28 capsules], 1 pack**

| 10759G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | .. | .. | 40.67 | 38.80 | [a] ESOMEPRAZOLE SANDOZ Hp7 [SZ] |

**esomeprazole 20 mg tablet: enteric [14 tablets] (&) clarithromycin 500 mg tablet [14 tablets] (&) amoxycillin 500 mg capsule [28 capsules], 1 pack**

| 8738X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | .. | .. | 40.67 | 38.80 | [a] Nexium Hp7 [AP] |

*Other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD)*

### ▪ SUCRALFATE

**sucralfate 1 g tablet, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2055E NP | 1 | 2 | .. | 26.68 | 27.89 | Carafate [AS] |

## ▪ DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

### BELLADONNA AND DERIVATIVES, PLAIN

*Belladonna alkaloids, tertiary amines*

### ▪ ATROPINE SULFATE

**ATROPINE Injection 600 micrograms in 1 mL, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5022H DP | 1 | .. | .. | 22.76 | 23.97 | Pfizer Australia Pty Ltd [PF] |

### ▪ ATROPINE SULFATE

**Note Shared Care Model**:

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

**ATROPINE Injection 600 micrograms in 1 mL, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1089H NP | 1 | 1 | .. | 22.76 | 23.97 | Pfizer Australia Pty Ltd [PF] |

### PROPULSIVES

*Propulsives*

### ▪ DOMPERIDONE

**domperidone 10 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1347X NP | 1 | .. | .. | 13.13 | 14.34 | Motilium [JC] |

### ▪ METOCLOPRAMIDE

**metoclopramide hydrochloride 10 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1207M NP MW | 1 | .. | .. | 12.22 | 13.43 | [a] APO-Metoclopramide [TX]<br>[a] Metoclopramide AN [EA]<br>[a] Pramin [AF] | [a] EMEXLON [RW]<br>[a] Metoclopramide RBX [RA] |
| | | | [B]1.91 | 14.13 | 13.43 | [a] Maxolon [IA] | |

**metoclopramide hydrochloride 10 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5151D DP | 1 | .. | .. | 12.22 | 13.43 | [a] APO-Metoclopramide [TX]<br>[a] Metoclopramide AN [EA]<br>[a] Pramin [AF] | [a] EMEXLON [RW]<br>[a] Metoclopramide RBX [RA] |
| | | | [B]1.91 | 14.13 | 13.43 | [a] Maxolon [IA] | |

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1206L NP MW | 1 | .. | .. | 16.80 | 18.01 | Maxolon [IA] |

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5153F DP | 1 | .. | .. | 16.80 | 18.01 | Maxolon [IA] |

## ▪ ANTIEMETICS AND ANTINAUSEANTS

### ANTIEMETICS AND ANTINAUSEANTS

*Serotonin (5HT3) antagonists*

### ▪ GRANISETRON

**Restricted benefit**

Nausea and vomiting

**Clinical criteria:**

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

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

**granisetron 3 mg/3 mL injection, 3 mL ampoule**

8729K NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 13.15 | 14.36 | [a] Granisetron-AFT [AE]<br>[a] Kytril [IX] | [a] Granisetron Kabi [PK] |

## ▪ GRANISETRON

**Authority required (STREAMLINED)**

***4092***

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with radiotherapy being used to treat malignancy.

**granisetron 3 mg/3 mL injection, 3 mL ampoule**

8730L NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 13.15 | 14.36 | [a] Granisetron-AFT [AE]<br>[a] Kytril [IX] | [a] Granisetron Kabi [PK] |

## ▪ GRANISETRON

**Authority required (STREAMLINED)**

***4102***

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with radiotherapy being used to treat malignancy.

**granisetron 2 mg tablet, 5**

8873B NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 55.66 | 38.80 | Kytril [IX] |

## ▪ GRANISETRON

**Restricted benefit**

Nausea and vomiting

**Clinical criteria:**

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

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

**granisetron 2 mg tablet, 1**

8728J NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *28.91 | 30.12 | Kytril [IX] |

## ▪ NETUPITANT + PALONOSETRON

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

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

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

**Authority required (STREAMLINED)**

***5991***

Nausea and vomiting

**Clinical criteria:**

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

No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

**Authority required (STREAMLINED)**

***5994***

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.

No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

**Authority required (STREAMLINED)**

***6937***

Nausea and vomiting

**Clinical criteria:**

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

No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

**Authority required (STREAMLINED)**

***6879***

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with dexamethasone on day 1 of a chemotherapy cycle, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.

No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

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

10731T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 115.56 | 38.80 | Akynzeo [MF] |

NP

## ▪ ONDANSETRON

**Authority required (STREAMLINED)**

***4102***

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with radiotherapy being used to treat malignancy.

**ondansetron 4 mg tablet, 10**

1594X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 20.26 | 21.47 | [a] APO-Ondansetron [TX]<br>[a] Ondansetron-DRLA [RZ]<br>[a] Onsetron 4 [ZP]<br>[a] Zofran [AS] | [a] Ondansetron AN [EA]<br>[a] Ondansetron SZ [HX]<br>[a] Zilfojim 4 [DO] |

NP

**ondansetron 8 mg tablet, 10**

1595Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 25.48 | 26.69 | [a] APO-Ondansetron [TX]<br>[a] Ondansetron-DRLA [RZ]<br>[a] Onsetron 8 [ZP]<br>[a] Zofran [AS] | [a] Ondansetron AN [EA]<br>[a] Ondansetron SZ [HX]<br>[a] Zilfojim 8 [DO] |

NP

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

8233H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 97.94 | 38.80 | Zofran syrup 50 mL [AS] |

NP

## ▪ ONDANSETRON

**Authority required (STREAMLINED)**

***4092***

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with radiotherapy being used to treat malignancy.

**ondansetron 8 mg/4 mL injection, 4 mL ampoule**

1597C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 11.64 | 12.85 | [a] Ondansetron Alphapharm [AF] | [a] Onsetron [ZP] |

NP

**ondansetron 4 mg/2 mL injection, 2 mL ampoule**

| 1596B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 11.43 | 12.64 | [a] Ondansetron Alphapharm [AF] | [a] Onsetron [ZP] |

## ▪ ONDANSETRON

**Restricted benefit**

Nausea and vomiting

**Clinical criteria:**

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

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

**ondansetron 4 mg tablet, 4**

| 8224W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 14.76 | 15.97 | [a] APO-Ondansetron [TX]<br>[a] Ondansetron-DRLA [RZ]<br>[a] Onsetron 4 [ZP] | [a] Ondansetron AN [EA]<br>[a] Ondansetron SZ [HX]<br>[a] Zofran [AS] |

**ondansetron 8 mg tablet, 4**

| 8225X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 16.84 | 18.05 | [a] APO-Ondansetron [TX]<br>[a] Ondansetron-DRLA [RZ]<br>[a] Onsetron 8 [ZP] | [a] Ondansetron AN [EA]<br>[a] Ondansetron SZ [HX]<br>[a] Zofran [AS] |

## ▪ ONDANSETRON

**Restricted benefit**

Nausea and vomiting

**Clinical criteria:**

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

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

**ondansetron 8 mg/4 mL injection, 4 mL ampoule**

| 8227B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 11.64 | 12.85 | [a] Ondansetron Alphapharm [AF] | [a] Onsetron [ZP] |

**ondansetron 4 mg/2 mL injection, 2 mL ampoule**

| 8226Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 11.43 | 12.64 | [a] Ondansetron Alphapharm [AF] | [a] Onsetron [ZP] |

## ▪ ONDANSETRON

**Restricted benefit**

Nausea and vomiting

**Clinical criteria:**

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

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

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

| 9441X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | .. | .. | 97.94 | 38.80 | Zofran syrup 50 mL [AS] |

## ▪ ONDANSETRON

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

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

**Restricted benefit**

Nausea and vomiting

**Clinical criteria:**

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

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

**ONDANSETRON Tablet (orally disintegrating) 8 mg, 4**

| 5471Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 16.84 | 18.05 | [a] Ondansetron AN ODT [EA] | [a] Ondansetron ODT-DRLA [RZ] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Ondansetron ODT GH [GQ] | [a] Ondansetron SZ ODT [HX] |
| | | | | | | [a] Onsetron ODT 8 [ED] | |

**ondansetron 4 mg wafer, 4**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8410P NP | 1 | .. | [B]2.45 | 17.21 | 15.97 | [a] Zofran Zydis [AS] |

**ondansetron 8 mg wafer, 4**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8411Q NP | 1 | .. | [B]2.45 | 19.29 | 18.05 | [a] Zofran Zydis [AS] |

**ONDANSETRON Tablet (orally disintegrating) 4 mg, 4**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5470X NP | 1 | .. | .. | 14.76 | 15.97 | [a] Ondansetron AN ODT [EA] | [a] Ondansetron ODT-DRLA [RZ] |
| | | | | | | [a] Ondansetron ODT GH [GQ] | [a] Ondansetron SZ ODT [HX] |
| | | | | | | [a] Onsetron ODT 4 [ED] | |

## ▪ ONDANSETRON

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

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

**Authority required (STREAMLINED)**

***5777***

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with radiotherapy being used to treat malignancy.

**ondansetron 4 mg wafer, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8412R NP | 1 | 1 | [B]2.45 | 22.71 | 21.47 | [a] Zofran Zydis [AS] |

**ondansetron 8 mg wafer, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8413T NP | 1 | 1 | [B]2.45 | 27.93 | 26.69 | [a] Zofran Zydis [AS] |

**ONDANSETRON Tablet (orally disintegrating) 4 mg, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5472B NP | 1 | 1 | .. | 20.26 | 21.47 | [a] Ondansetron AN ODT [EA] | [a] Ondansetron ODT-DRLA [RZ] |
| | | | | | | [a] Ondansetron ODT GH [GQ] | [a] Ondansetron SZ ODT [HX] |
| | | | | | | [a] Onsetron ODT 4 [ED] | [a] Zilfojim ODT 4 [DO] |

**ONDANSETRON Tablet (orally disintegrating) 8 mg, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5473C NP | 1 | 1 | .. | 25.48 | 26.69 | [a] Ondansetron AN ODT [EA] | [a] Ondansetron ODT-DRLA [RZ] |
| | | | | | | [a] Ondansetron ODT GH [GQ] | [a] Ondansetron SZ ODT [HX] |
| | | | | | | [a] Onsetron ODT 8 [ED] | [a] Zilfojim ODT 8 [DO] |

## ▪ PALONOSETRON

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

**Note** This drug is not PBS-subsidised for administration with oral 5-HT3 antagonists.

**Restricted benefit**

Nausea and vomiting

**Clinical criteria:**

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

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5295Q NP | 1 | .. | .. | 46.18 | 38.80 | Aloxi [MF] |

## ▪ TROPISETRON

**Restricted benefit**

Nausea and vomiting

**Clinical criteria:**

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

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

**tropisetron 5 mg/5 mL injection, 5 mL ampoule**

| 2746M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 16.00 | 17.21 | Tropisetron-AFT [AE] |

*Other antiemetics*

## ▪ APREPITANT

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

**Authority required (STREAMLINED)**

***4211***

Nausea and vomiting

**Clinical criteria:**

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

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

**Authority required (STREAMLINED)**

***4215***

Nausea and vomiting

**Clinical criteria:**

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

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

**Authority required (STREAMLINED)**

***6444***

Nausea and vomiting

**Clinical criteria:**

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

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

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

**Authority required (STREAMLINED)**

***6370***

Nausea and vomiting

**Clinical criteria:**

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

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

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

**aprepitant 165 mg capsule, 1**

| 2518M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 115.56 | 38.80 | Emend [MK] |

## ▪ FOSAPREPITANT

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

**Authority required (STREAMLINED)**

***6886***

Nausea and vomiting

**Clinical criteria:**

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

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

**Authority required (STREAMLINED)**

***6891***

Nausea and vomiting

**Clinical criteria:**

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

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

**Authority required (STREAMLINED)**

***6887***

Nausea and vomiting

**Clinical criteria:**

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

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

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

**Authority required (STREAMLINED)**

***6852***

Nausea and vomiting

**Clinical criteria:**

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

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

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

**fosaprepitant 150 mg injection, 1 vial**

| 11107N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 115.56 | 38.80 | Emend IV [MK] |

## ▪ PROCHLORPERAZINE

**Caution** Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only.

**prochlorperazine maleate 5 mg tablet, 25**

| 5205Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 12.06 | 13.27 | [a] APO-Prochlorperazine [TX]<br>[a] Prochlorperazine AN [EA]<br>[a] Prochlorperazine GH [GQ] | [a] ProCalm [RW]<br>[a] Prochlorperazine-GA [ED]<br>[a] Stemzine [AV] |
| | | | [B]2.67 | 14.73 | 13.27 | [a] Stemetil [SW] | |

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

| 5206B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 20.77 | 21.98 | Stemetil [SW] |

## ▪ PROCHLORPERAZINE

**Caution** Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only.

**Note** As prochlorperazine may be associated with parkinsonism and tardive dyskinesia it should be used for short-term treatment only. However, authorities for increased maximum quantities and/or repeats of prochlorperazine tablets will be granted for the treatment of emesis associated with malignant disease.

**prochlorperazine maleate 5 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2893G NP | 1 | .. | .. | 12.06 | 13.27 | [a] APO-Prochlorperazine [TX]<br>[a] Prochlorperazine AN [EA]<br>[a] Prochlorperazine GH [GQ] | [a] ProCalm [RW]<br>[a] Prochlorperazine-GA [ED]<br>[a] Stemzine [AV] |
| | | | [B]2.67 | 14.73 | 13.27 | [a] Stemetil [SW] | |

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2369Q NP | 1 | .. | .. | 20.77 | 21.98 | Stemetil [SW] |

## ▪ PROMETHAZINE

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3374N DP | 2 | .. | .. | *38.67 | 38.80 | Hospira Pty Limited [PF] |

# ▪ BILE AND LIVER THERAPY

## BILE THERAPY

*Bile acid preparations*

## ▪ URSODEOXYCHOLIC ACID

**Note** Not for use in the treatment of sclerosing cholangitis or cholelithiasis.

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***5757***

Primary biliary cirrhosis

**ursodeoxycholic acid 500 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11180K NP | 1 | 2 | .. | 288.57 | 38.80 | Ursofalk [OA] |

**ursodeoxycholic acid 250 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8448P NP | 2 | 2 | .. | *307.49 | 38.80 | [a] APO-Ursodeoxycholic acid [TX]<br>[a] Ursofalk [OA] | [a] Ursodox GH [GQ]<br>[a] Ursosan [BZ] |

# ▪ DRUGS FOR CONSTIPATION

## DRUGS FOR CONSTIPATION

*Contact laxatives*

## ▪ BISACODYL

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

Terminal malignant neoplasia

**Restricted benefit**

Anorectal congenital abnormalities

**Restricted benefit**

Megacolon

**bisacodyl 5 mg enteric tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1259G NP | 1 | 2 | .. | 16.36 | 17.57 | Lax-Tab [AE] |

## ▪ BISACODYL

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Terminal malignant neoplasia

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Anorectal congenital abnormalities

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Megacolon

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**bisacodyl 10 mg suppository, 12**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1258F NP | 3 | 4 | .. | *21.43 | 22.64 | Petrus Bisacodyl Suppositories [PP] |

**bisacodyl 10 mg suppository, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1260H NP | 3 | 5 | .. | *23.71 | 24.92 [a] | Petrus Bisacodyl Suppositories [PP] |
| | | | [B]1.29 | *25.00 | 24.92 [a] | Dulcolax [VZ] |

*Bulk-forming laxatives*

## ▪ RHAMNUS FRANGULA + STERCULIA

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

Terminal malignant neoplasia

**Restricted benefit**

Anorectal congenital abnormalities

**Restricted benefit**

Megacolon

**rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1104D NP | ‡1 | 1 | .. | 27.57 | 28.78 | Normacol Plus [NE] |

*Osmotically acting laxatives*

## ▪ MACROGOL-3350

**Note** Pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 510 g and pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets are equivalent for the purposes of substitution.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must have malignant neoplasia.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function, **AND**
- The condition must be unresponsive to other oral therapies.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

Chronic constipation

**Clinical criteria:**

- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**Restricted benefit**

Faecal impaction

**Clinical criteria:**

- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**macrogol-3350 1 g/g powder for oral liquid, 510 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3416T NP | ‡1 | 5 | .. | 18.66 | 19.87 | [a] OsmoLax [KY] |

**macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2373X NP | ‡1 | 5 | .. | 18.66 | 19.87 | [a] Herron ClearLax [ON] |

## ▪ MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must have malignant neoplasia.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function, **AND**
- The condition must be unresponsive to other oral therapies.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

Chronic constipation

**Clinical criteria:**

- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**Restricted benefit**

Faecal impaction

**Clinical criteria:**

- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets**

8612G NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 5 | .. | 18.66 | 19.87 | [a] APO-MACROGOL plus ELECTROLYTES [TX]<br>[a] LaxaCon [EA]<br>[a] Macrovic [RF]<br>[a] Movicol [NE] | [a] Chemists' Own Macrogol with Electrolytes [RW]<br>[a] lax-sachets [AE]<br>[a] Molaxole [HM] |

**macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL**

10126Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *21.17 | 22.38 | Movicol Liquid [NE] |

*Enemas*

## ▪ BISACODYL

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

Terminal malignant neoplasia

**Restricted benefit**

Anorectal congenital abnormalities

**Restricted benefit**

Megacolon

**bisacodyl 10 mg/5 mL enema, 25 x 5 mL**

1263L NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 38.50 | 38.80 | Bisalax [AS] |

## ▪ SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

Terminal malignant neoplasia

**Restricted benefit**

Anorectal congenital abnormalities

**Restricted benefit**

Megacolon

**sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2091C NP | 2 | 2 | .. | *29.35 | 30.56 | Micolette [AE] |

## ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS

### INTESTINAL ANTIINFECTIVES

*Antibiotics*

### NYSTATIN

**nystatin 500 000 units tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1696G NP | 1 | .. | .. | 20.64 | 21.85 | Nilstat [QA] |

**nystatin 500 000 units tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3342X DP | 1 | .. | .. | 20.64 | 21.85 | Nilstat [QA] |

**nystatin 500 000 units capsule, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1699K NP | 1 | .. | .. | 20.64 | 21.85 | Nilstat [QA] |

**nystatin 500 000 units capsule, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3345C DP | 1 | .. | .. | 20.64 | 21.85 | Nilstat [QA] |

### RIFAXIMIN

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

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

**Authority required**

Prevention of hepatic encephalopathy

**Treatment criteria:**

- Must be treated by a gastroenterologist or hepatologist or in consultation with a gastroenterologist or hepatologist.

**Clinical criteria:**

- The treatment must be in combination with lactulose, if lactulose is tolerated, **AND**
- Patient must have had prior episodes of hepatic encephalopathy.

**rifaximin 550 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10001J | 1 | 5 | .. | 490.78 | 38.80 | Xifaxan [NE] |

### VANCOMYCIN

**Note** Metronidazole has similar efficacy to vancomycin but may have less selective pressure to vancomycin resistant enterococci and is therefore the preferred treatment.

**Authority required**

Antibiotic associated pseudomembranous colitis

**Clinical criteria:**

- The condition must be due to **Clostridium difficile**, **AND**
- The condition must be unresponsive to metronidazole.

**Authority required**

Antibiotic associated pseudomembranous colitis

**Clinical criteria:**

- The condition must be due to **Clostridium difficile**, **AND**
- Patient must have an intolerance to metronidazole.

**vancomycin 125 mg capsule, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3113W | 2 | .. | .. | *219.91 | 38.80 | Vancocin [AS] |

**vancomycin 250 mg capsule, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3114X | 2 | .. | .. | *434.95 | 38.80 | Vancocin [AS] |

## ELECTROLYTES WITH CARBOHYDRATES

*Oral rehydration salt formulations*

### ▪ SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRIC ACID

**Authority required**

Rehydration in intestinal failure

**sodium chloride 470 mg + potassium chloride 300 mg + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11049M | 30 | .. | .. | *155.35 | 38.80 | [a] Repalyte New Formulation [SW] | [a] restore O.R.S. [EA] |

### ▪ SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRIC ACID

**Note** Each sachet contains sodium chloride 470 mg, potassium chloride 300 mg, sodium acid citrate 530 mg and glucose 3.56 g.

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**sodium chloride 470 mg + potassium chloride 300 mg + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3196F NP | ‡1 | .. | .. | 15.90 | 17.11 | [a] O.R.S. [AS] | [a] Repalyte New Formulation [SW] |
| | | | | | | [a] restore O.R.S. [EA] | |

## ANTIPROPULSIVES

*Antipropulsives*

### ▪ DIPHENOXYLATE + ATROPINE SULFATE

**diphenoxylate hydrochloride 2.5 mg + atropine sulfate 25 microgram tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2501P NP | 1 | .. | .. | 12.87 | 14.08 | [a] Lofenoxal [IA] |
| | | | [B]1.51 | 14.38 | 14.08 | [a] Lomotil [IV] |

### ▪ LOPERAMIDE

**Authority required (STREAMLINED)**

***6364***

Diarrhoea

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**loperamide hydrochloride 2 mg capsule, 12**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1571Q NP | 1 | .. | .. | 12.58 | 13.79 | [a] Gastrex [CR] | [a] Gastro-Stop Loperamide [AS] |
| | | | [B]0.65 | 13.23 | 13.79 | [a] Imodium [JT] | |

### ▪ LOPERAMIDE

**Authority required**

Diarrhoea

**loperamide hydrochloride 2 mg capsule, 12**

| 10889D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 5 | .. | .. | *18.55 | 19.76 | [a] Gastrex [CR] | [a] Gastro-Stop Loperamide [AS] |
| | | | [B]3.25 | *21.80 | 19.76 | [a] Imodium [JT] | |

## INTESTINAL ANTIINFLAMMATORY AGENTS

*Corticosteroids acting locally*

### ▪ BUDESONIDE

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

**budesonide 2 mg/application enema, 2 x 14 applications**

| 10034D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 3 | .. | 188.64 | 38.80 | Budenofalk [OA] |

### ▪ HYDROCORTISONE ACETATE

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

**Restricted benefit**
Proctitis
**Restricted benefit**
Ulcerative colitis

**hydrocortisone acetate 10% enema, 21.1 g**

| 1502C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 3 | .. | *40.67 | 38.80 | Colifoam [HM] |

### ▪ PREDNISOLONE SODIUM PHOSPHATE

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

**prednisolone (as sodium phosphate) 20 mg/100 mL enema, 7 x 100 mL**

| 1920C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 3 | .. | *198.27 | 38.80 | Predsol [QA] |

### ▪ PREDNISOLONE SODIUM PHOSPHATE

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

**Restricted benefit**
Proctitis
**Restricted benefit**
Ulcerative colitis

**prednisolone (as sodium phosphate) 5 mg suppository, 10**

| 2554K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 3 | .. | *41.86 | 38.80 | Predsol [QA] |

*Aminosalicylic acid and similar agents*

### ▪ BALSALAZIDE

**Note** Not for the treatment of Crohn disease
**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***4824***
Ulcerative colitis
**Clinical criteria:**

- Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR
- Patient must be intolerant to sulfasalazine.

**balsalazide sodium 750 mg capsule, 180**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8845M NP | 1 | 5 | .. | 113.36 | 38.80 | Colazide [PK] |

## ▪ MESALAZINE

**Note** Not for the treatment of Crohn disease

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***4824***

Ulcerative colitis

**Clinical criteria:**

- Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR
- Patient must be intolerant to sulfasalazine.

**mesalazine 1.5 g granules, 60 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9206M NP | 1 | 5 | .. | 221.60 | 38.80 | Salofalk [OA] |

**mesalazine 500 mg granules, 100 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8598M NP | 2 | 5 | .. | *273.23 | 38.80 | Salofalk [OA] |

**mesalazine 4 g modified release granules, 30 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10254Q NP | 1 | 5 | .. | 287.85 | 38.80 | Pentasa [FP] |

**mesalazine 1.2 g modified release tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9353G NP | 2 | 5 | .. | *391.35 | 38.80 | Mezavant [ZI] |

**mesalazine 1 g modified release granules, 100 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8599N NP | 1 | 5 | .. | 255.73 | 38.80 | Salofalk [OA] |

**mesalazine 3 g granules, 30 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10257W NP | 1 | 5 | .. | 221.60 | 38.80 | Salofalk [OA] |

## ▪ MESALAZINE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***4873***

Ulcerative colitis

**Clinical criteria:**

- Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR
- Patient must be intolerant to sulfasalazine.

**Authority required (STREAMLINED)**

***4896***

Crohn disease

**Clinical criteria:**

- Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR
- Patient must be intolerant to sulfasalazine.

**mesalazine 250 mg enteric tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1611T NP | 1 | 5 | .. | 86.24 | 38.80 | Mesasal [AS] |

**mesalazine 2 g modified release granules, 60 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2287J NP | 1 | 5 | .. | 287.85 | 38.80 | Pentasa [FP] |

**mesalazine 500 mg enteric tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8731M NP | 2 | 5 | .. | *273.23 | 38.80 | Salofalk [OA] |

**mesalazine 500 mg modified release tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2214M NP | 2 | 5 | .. | *273.23 | 38.80 | Pentasa [FP] |

**mesalazine 1 g modified release granules, 120 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2234N NP | 1 | 5 | .. | 305.91 | 38.80 | Pentasa [FP] |

**mesalazine 1 g modified release tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3413P NP | 2 | 5 | .. | *305.91 | 38.80 | Pentasa [FP] |

## ▪ MESALAZINE

**Note** Not for the treatment of Crohn disease

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

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

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Acute episode of mild to moderate ulcerative proctitis

**mesalazine 1 g suppository, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5461K NP | 1 | 1 | .. | 123.34 | 38.80 | Salofalk [OA] |

**mesalazine 1 g suppository, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8752P NP | 1 | 1 | .. | 123.34 | 38.80 | Pentasa [FP] |

## ▪ MESALAZINE

**Note** Not for the treatment of Crohn disease

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

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

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***4888***

Acute episode of mild to moderate ulcerative colitis

**mesalazine 4 g/60 mL enema, 7 x 60 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8617M NP | 4 | 1 | .. | *419.19 | 38.80 | Salofalk [OA] |

**mesalazine 2 g/60 mL enema, 7 x 60 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8616L NP | 4 | 1 | .. | *311.39 | 38.80 | Salofalk [OA] |

**mesalazine 1 g/application enema, 14 applications**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8768L NP | 4 | 1 | .. | *311.39 | 38.80 | Salofalk [OA] |

**mesalazine 1 g/100 mL enema, 7 x 100 mL**

| 8753Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 1 | .. | *311.39 | 38.80 | Pentasa [FP] |

## ▪ OLSALAZINE

**Note** Not for the treatment of Crohn disease

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***4824***

Ulcerative colitis

**Clinical criteria:**

- Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR
- Patient must be intolerant to sulfasalazine.

**olsalazine sodium 250 mg capsule, 100**

| 1728Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 58.58 | 38.80 | Dipentum [IX] |

**olsalazine sodium 500 mg tablet, 100**

| 8086N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 94.75 | 38.80 | Dipentum [IX] |

## ▪ SULFASALAZINE

**Note Continuing Therapy Only:**

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

**sulfasalazine 500 mg tablet, 100**

| 2093E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *50.45 | 38.80 | Salazopyrin [PF] |

**SULFASALAZINE Tablet 500 mg (enteric coated), 100**

| 2096H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *54.43 | 38.80 | [a] Pyralin EN [FZ] |
| | | | [B]4.00 | *58.43 | 38.80 | [a] Salazopyrin-EN [PF] |

## ▪ SULFASALAZINE

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

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

**Restricted benefit**

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**sulfasalazine 500 mg tablet, 100**

| 9208P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 11 | .. | *50.45 | 38.80 | Salazopyrin [PF] |

**SULFASALAZINE Tablet 500 mg (enteric coated), 100**

| 9209Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 11 | .. | *54.43 | 38.80 | [a] Pyralin EN [FZ] |
| | | | [B]4.00 | *58.43 | 38.80 | [a] Salazopyrin-EN [PF] |

# ▪ DIGESTIVES, INCL. ENZYMES

## DIGESTIVES, INCL. ENZYMES

*Enzyme preparations*

## ▪ PANCREATIC EXTRACT

**Note Continuing Therapy Only:**

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

**pancreatic extract 25 000 units modified release capsule, 100**

| 8021E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 10 | .. | *133.15 | 38.80 | Creon 25,000 [GO] |

**pancreatic extract 10 000 units modified release capsule, 100**

| 8020D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 5 | 10 | .. | *164.20 | 38.80 | Creon 10,000 [GO] |

**pancreatic extract 40 000 units modified release capsule, 100**

| 9412J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 10 | .. | *206.89 | 38.80 | Creon 40,000 [GO] |

**pancreatic extract 5000 units/100 mg enteric coated granules, 20 g**

| 5453B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 10 | .. | *127.99 | 38.80 | Creon Micro [GO] |

## ▪ PANCREATIC EXTRACT

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

**Restricted benefit**
Cystic fibrosis
**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**pancreatic extract 25 000 units modified release capsule, 100**

| 9227P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 21 | .. | *133.15 | 38.80 | Creon 25,000 [GO] |

**pancreatic extract 10 000 units modified release capsule, 100**

| 9226N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 5 | 21 | .. | *164.20 | 38.80 | Creon 10,000 [GO] |

**pancreatic extract 40 000 units modified release capsule, 100**

| 9413K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 21 | .. | *206.89 | 38.80 | Creon 40,000 [GO] |

**pancreatic extract 5000 units/100 mg enteric coated granules, 20 g**

| 5454C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 21 | .. | *127.99 | 38.80 | Creon Micro [GO] |

## ▪ PANCRELIPASE

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

**pancrelipase 25 000 units capsule, 100**

| 8366H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 10 | .. | *124.63 | 38.80 | Panzytrat 25000 [TM] |

## ▪ PANCRELIPASE

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

**Restricted benefit**
Cystic fibrosis
**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**pancrelipase 25 000 units capsule, 100**

| 9229R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 21 | .. | *124.63 | 38.80 | Panzytrat 25000 [TM] |

# DRUGS USED IN DIABETES

## INSULINS AND ANALOGUES

*Insulins and analogues for injection, fast-acting*

### INSULIN ASPART

**insulin aspart 100 units/mL injection, 5 x 3 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8435Y NP | 5 | 1 | .. | *240.60 | 38.80 | NovoRapid FlexPen [NF] | NovoRapid Penfill 3 mL [NO] |

**insulin aspart 100 units/mL injection, 1 x 10 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8571D NP | 5 | 2 | .. | *143.15 | 38.80 | NovoRapid [NO] |

### INSULIN GLULISINE

**insulin glulisine 100 units/mL injection, 5 x 3 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1921D NP | 5 | 1 | .. | *240.60 | 38.80 | Apidra [AV] | Apidra SoloStar [SW] |

**insulin glulisine 100 units/mL injection, 1 x 10 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9224L NP | 5 | 2 | .. | *143.15 | 38.80 | Apidra [SW] |

### INSULIN LISPRO

**insulin lispro 100 units/mL injection, 5 x 3 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8212F NP | 5 | 1 | .. | *240.60 | 38.80 | Humalog [LY] | Humalog KwikPen [KP] |

**insulin lispro 100 units/mL injection, 1 x 10 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8084L NP | 5 | 2 | .. | *143.15 | 38.80 | Humalog [LY] |

### INSULIN NEUTRAL BOVINE

**Authority required**

Diabetes mellitus

**Clinical criteria:**

- Patient must be intolerant to human insulin.

**insulin neutral bovine 100 units/mL injection, 1 x 10 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1713E NP | 5 | 2 | .. | *394.25 | 38.80 | Hypurin Neutral [AS] |

### INSULIN NEUTRAL HUMAN

**insulin neutral human 100 units/mL injection, 5 x 3 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1762R NP | 5 | 1 | .. | *201.35 | 38.80 | Actrapid Penfill 3 mL [NO] | Humulin R [LY] |

**insulin neutral human 100 units/mL injection, 1 x 10 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1531N NP | 5 | 2 | .. | *121.10 | 38.80 | Actrapid [NO] | Humulin R [LY] |

*Insulins and analogues for injection, intermediate-acting*

### INSULIN ISOPHANE BOVINE

**Authority required**

Diabetes mellitus

**Clinical criteria:**

- Patient must be intolerant to human insulin.

**insulin isophane bovine 100 units/mL injection, 1 x 10 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1711C NP | 5 | 2 | .. | *394.25 | 38.80 | Hypurin Isophane [AS] |

## ▪ INSULIN ISOPHANE HUMAN

**insulin isophane human 100 units/mL injection, 1 x 10 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1533Q NP | 5 | 2 | .. | *121.10 | 38.80 | Humulin NPH [LY] | Protaphane [NO] |

**insulin isophane human 100 units/mL injection, 5 x 3 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1761Q NP | 5 | 1 | .. | *201.35 | 38.80 | Humulin NPH [LY]<br>Protaphane Penfill 3 mL [NO] | Protaphane InnoLet [NI] |

*Insulins and analogues for injection, intermediate- or long-acting combined with fast-acting*

## ▪ INSULIN ASPART + INSULIN ASPART PROTAMINE

**insulin aspart 30 units/mL + insulin aspart protamine 70 units/mL injection, 5 x 3 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8609D NP | 5 | 1 | .. | *240.60 | 38.80 | NovoMix 30 FlexPen [NF] | NovoMix 30 Penfill 3 mL [NO] |

## ▪ INSULIN ISOPHANE HUMAN + INSULIN NEUTRAL HUMAN

**insulin neutral human 50 units/mL + insulin isophane human 50 units/mL injection, 5 x 3 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2062M NP | 5 | 1 | .. | *201.35 | 38.80 | Mixtard 50/50 Penfill 3 mL [NO] |

**insulin isophane human 70 units/mL + insulin neutral human 30 units/mL injection, 5 x 3 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1763T NP | 5 | 1 | .. | *201.35 | 38.80 | Humulin 30/70 [LY]<br>Mixtard 30/70 Penfill 3 mL [NO] | Mixtard 30/70 InnoLet [NI] |

**insulin neutral human 30 units/mL + insulin isophane human 70 units/mL injection, 1 x 10 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1426C NP | 5 | 2 | .. | *121.10 | 38.80 | Humulin 30/70 [LY] |

## ▪ INSULIN LISPRO + INSULIN LISPRO PROTAMINE

**insulin lispro 25 units/mL + insulin lispro protamine 75 units/mL injection, 5 x 3 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8390N NP | 5 | 1 | .. | *240.60 | 38.80 | Humalog Mix25 [LY] | Humalog Mix25 KwikPen [KP] |

**insulin lispro 50 units/mL + insulin lispro protamine 50 units/mL injection, 5 x 3 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8874C NP | 5 | 1 | .. | *240.60 | 38.80 | Humalog Mix50 [LY] | Humalog Mix50 KwikPen [KP] |

*Insulins and analogues for injection, long-acting*

## ▪ INSULIN DETEMIR

**Restricted benefit**
Type 1 diabetes

**insulin detemir 100 units/mL injection, 5 x 3 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9040T NP | 5 | 1 | .. | *385.65 | 38.80 | Levemir FlexPen [NF] | Levemir Penfill [NO] |

## ▪ INSULIN GLARGINE

**insulin glargine 100 units/mL injection, 5 x 3 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9039R NP | 5 | 1 | .. | *406.25 | 38.80 | Lantus [SW] | Lantus SoloStar [AV] |

# BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS

*Biguanides*

## ▪ METFORMIN

**metformin hydrochloride 1 g tablet, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8607B NP | 1 | 5 | .. | 15.78 | 16.99 | [a] APO-Metformin 1000 [TX] | [a] Chem mart Metformin 1000 [CH] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Diaformin 1000 [AF] | [a] Formet 1000 [RW] |
| | | | | | | [a] Glucobete 1000 [DO] | [a] Metformin AN [EA] |
| | | | | | | [a] Metformin-GA [ED] | [a] Metformin generichealth 1000 [GQ] |
| | | | | | | [a] Metformin Ranbaxy 1000 [RA] | [a] Metformin Sandoz [SZ] |
| | | | | | | [a] Pharmacor Metformin 1000 [CR] | [a] Terry White Chemists Metformin 1000 [TW] |
| | | | [B]4.95 | 20.73 | 16.99 | [a] Diabex 1000 [AL] | |

**metformin hydrochloride 500 mg modified release tablet, 120**

| 9435N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.40 | 16.61 | [a] APO-Metformin XR 500 [TX] | [a] Blooms the Chemist Metformin XR 500 [IB] |
| | | | | | | [a] Chem mart Metformin XR 500 [CH] | [a] Diaformin XR [AF] |
| | | | | | | [a] Metex XR [RW] | [a] Metformin XR 500 APOTEX [GX] |
| | | | | | | [a] Terry White Chemists Metformin XR 500 [TW] | |
| | | | [B]4.95 | 20.35 | 16.61 | [a] Diabex XR [AL] | |

**metformin hydrochloride 500 mg tablet, 100**

| 2430X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 13.78 | 14.99 | [a] APO-Metformin 500 [TX] | [a] Chem mart Metformin [CH] |
| | | | | | | [a] Diaformin [AF] | [a] FORMET 500 [RF] |
| | | | | | | [a] Formet Aspen 500 [RW] | [a] Glucobete 500 [DO] |
| | | | | | | [a] Metformin 500 [CR] | [a] Metformin AN [EA] |
| | | | | | | [a] Metformin-GA [ED] | [a] Metformin generichealth [GQ] |
| | | | | | | [a] Metformin Ranbaxy [RA] | [a] Metformin Sandoz [SZ] |
| | | | | | | [a] Terry White Chemists Metformin [TW] | |
| | | | [B]4.95 | 18.73 | 14.99 | [a] Diabex [AL] | |

**metformin hydrochloride 850 mg tablet, 60**

| 1801T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 13.78 | 14.99 | [a] APO-Metformin 850 [TX] | [a] Chem mart Metformin [CH] |
| | | | | | | [a] Diaformin 850 [AF] | [a] FORMET 850 [RF] |
| | | | | | | [a] Formet Aspen 850 [RW] | [a] Glucobete 850 [DO] |
| | | | | | | [a] Metformin 850 [CR] | [a] Metformin AN [EA] |
| | | | | | | [a] Metformin-GA [ED] | [a] Metformin Sandoz [SZ] |
| | | | | | | [a] Terry White Chemists Metformin [TW] | |
| | | | [B]4.95 | 18.73 | 14.99 | [a] Diabex 850 [AL] | |

**metformin hydrochloride 1 g modified release tablet, 60**

| 3439B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.40 | 16.61 | [a] APO-Metformin XR 1000 [TX] | [a] Blooms the Chemist Metformin XR 1000 [IB] |
| | | | | | | [a] Chem mart Metformin XR 1000 [CH] | [a] Diaformin XR 1000 [AF] |
| | | | | | | [a] METEX XR 1000 [RW] | [a] Terry White Chemists Metformin XR 1000 [TW] |
| | | | [B]4.95 | 20.35 | 16.61 | [a] Diabex XR 1000 [AL] | |

*Sulfonylureas*

## ▪ GLIBENCLAMIDE

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

**glibenclamide 5 mg tablet, 100**

| 2939Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.41 | 16.62 | Daonil [SW] |

## ▪ GLICLAZIDE

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

**gliclazide 30 mg modified release tablet, 100**

| 8535F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.12 | 18.33 | [a] APO-Gliclazide MR [TX] | [a] Chem mart Gliclazide MR [CH] |
| | | | | | | [a] Glyade MR [AF] | [a] Terry White Chemists Gliclazide MR [TW] |

**gliclazide 80 mg tablet, 100**

| 2449X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.95 | 18.16 | [a] Chem mart Gliclazide [CH]<br>[a] Glyade [AF]<br>[a] Terry White Chemists Gliclazide [TW] | [a] GenRx Gliclazide [GX]<br>[a] Nidem [RW] |

**gliclazide 60 mg modified release tablet, 60**

| 9302N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 18.33 | 19.54 | [a] ARDIX GLICLAZIDE 60mg MR [RX] |
| | | | [B]4.95 | 23.28 | 19.54 | [a] Diamicron 60mg MR [SE] |

## ▪ GLIMEPIRIDE

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

**glimepiride 3 mg tablet, 30**

| 8533D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 13.44 | 14.65 | [a] APO-Glimepiride [TX]<br>[a] Diapride 3 [RW]<br>[a] Glimepiride AN [EA] | [a] Aylide 3 [AF]<br>[a] Dimirel [AV]<br>[a] Glimepiride Sandoz [SZ] |
| | | | [B]2.19 | 15.63 | 14.65 | [a] Amaryl [SW] | |

**glimepiride 2 mg tablet, 30**

| 8451T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 12.94 | 14.15 | [a] APO-Glimepiride [TX]<br>[a] Diapride 2 [RW]<br>[a] Glimepiride AN [EA] | [a] Aylide 2 [AF]<br>[a] Dimirel [AV]<br>[a] Glimepiride Sandoz [SZ] |
| | | | [B]2.18 | 15.12 | 14.15 | [a] Amaryl [SW] | |

**glimepiride 4 mg tablet, 30**

| 8452W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 13.99 | 15.20 | [a] APO-Glimepiride [TX]<br>[a] Diapride 4 [RW]<br>[a] Glimepiride AN [EA] | [a] Aylide 4 [AF]<br>[a] Dimirel [AV]<br>[a] Glimepiride Sandoz [SZ] |
| | | | [B]2.19 | 16.18 | 15.20 | [a] Amaryl [SW] | |

**glimepiride 1 mg tablet, 30**

| 8450R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 12.06 | 13.27 | [a] APO-Glimepiride [TX]<br>[a] Diapride 1 [RW]<br>[a] Glimepiride AN [EA] | [a] Aylide 1 [AF]<br>[a] Dimirel [AV]<br>[a] Glimepiride Sandoz [SZ] |
| | | | [B]2.23 | 14.29 | 13.27 | [a] Amaryl [SW] | |

## ▪ GLIPIZIDE

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

**glipizide 5 mg tablet, 100**

| 2440K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.91 | 19.12 | [a] Melizide [AF] |
| | | | [B]8.50 | 26.41 | 19.12 | [a] Minidiab [PF] |

*Combinations of oral blood glucose lowering drugs*

## ▪ ALOGLIPTIN + METFORMIN

**Note** This fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

**Authority required (STREAMLINED)**

***4423***

Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Authority required (STREAMLINED)**

***4427***

Diabetes mellitus type 2

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and alogliptin.

**alogliptin 12.5 mg + metformin hydrochloride 1 g tablet, 56**

| 10035E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 61.68 | 38.80 | Nesina Met 12.5/1000 [TK] |

**alogliptin 12.5 mg + metformin hydrochloride 850 mg tablet, 56**

| 10032B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 61.27 | 38.80 | Nesina Met 12.5/850 [TK] |

**alogliptin 12.5 mg + metformin hydrochloride 500 mg tablet, 56**

| 10033C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 60.27 | 38.80 | Nesina Met 12.5/500 [TK] |

## ▪ DAPAGLIFLOZIN + METFORMIN

**Note Continuing Therapy Only:**

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

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**Authority required (STREAMLINED)**

***5631***

Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

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**Authority required (STREAMLINED)**

***5739***

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and dapagliflozin.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

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**Authority required (STREAMLINED)**

***5798***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**Authority required (STREAMLINED)**

***5657***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Note** This fixed dose combination is not PBS-subsidised as initial therapy or for use in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

**dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56**

| 10510E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 61.18 | 38.80 | Xigduo XR 5/1000 [AP] |

**dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28**

| 10516L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 59.02 | 38.80 | Xigduo XR 10/500 [AP] |

**dapagliflozin 10 mg + metformin hydrochloride 1 g modified release tablet, 28**

| 10515K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 59.78 | 38.80 | Xigduo XR 10/1000 [AP] |

## ▪ EMPAGLIFLOZIN + METFORMIN

**Note** A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

***5953***

Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60**

10640B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 64.76 | 38.80 | Jardiamet 12.5 mg/1000 mg [BY] |

**empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60**

10639Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 63.25 | 38.80 | Jardiamet 12.5 mg/500 mg [BY] |

**empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60**

10649L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 64.76 | 38.80 | Jardiamet 5 mg/1000 mg [BY] |

**empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60**

10650M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 63.25 | 38.80 | Jardiamet 5 mg/500 mg [BY] |

## ▪ EMPAGLIFLOZIN + METFORMIN

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***5966***

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and empagliflozin.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

***5798***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**Authority required (STREAMLINED)**

***5657***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Note** This fixed dose combination is not PBS-subsidised as initial therapy or for use in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

**empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60**

| 10677Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 64.76 | 38.80 | Jardiamet 12.5 mg/1000 mg [BY] |

**empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60**

| 10633P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 63.25 | 38.80 | Jardiamet 12.5 mg/500 mg [BY] |

**empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60**

| 10627H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 64.76 | 38.80 | Jardiamet 5 mg/1000 mg [BY] |

**empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60**

| 10626G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 63.25 | 38.80 | Jardiamet 5 mg/500 mg [BY] |

## ▪ LINAGLIPTIN + METFORMIN

**Note** This fixed dose combination tablet is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6333***

Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Authority required (STREAMLINED)**

***6336***

Diabetes mellitus type 2

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and linagliptin.

**Authority required (STREAMLINED)**

***6344***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

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**Authority required (STREAMLINED)**

***6443***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60**

| 10045Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 62.30 | 38.80 | Trajentamet [BY] |

**linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60**

| 10038H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 61.23 | 38.80 | Trajentamet [BY] |

**linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60**

| 10044P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 62.74 | 38.80 | Trajentamet [BY] |

## ▪ METFORMIN + GLIBENCLAMIDE

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

**metformin hydrochloride 500 mg + glibenclamide 5 mg tablet, 90**

| 8811R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 18.42 | 19.63 | Glucovance 500mg/5mg [AL] |

**metformin hydrochloride 500 mg + glibenclamide 2.5 mg tablet, 90**

| 8810Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.43 | 18.64 | Glucovance 500mg/2.5mg [AL] |

**metformin hydrochloride 250 mg + glibenclamide 1.25 mg tablet, 90**

| 8838E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.72 | 17.93 | Glucovance 250mg/1.25mg [AL] |

## ▪ ROSIGLITAZONE + METFORMIN

**Note** This fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a glucagon-like peptide-1, an insulin or an SGLT2 inhibitor.

**Authority required**

Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have a contraindication to a sulfonylurea; OR
- Patient must not have tolerated a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with metformin; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**rosiglitazone 2 mg + metformin hydrochloride 500 mg tablet, 56**

| 9059T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 59.86 | 38.80 | Avandamet [GK] |

**rosiglitazone 2 mg + metformin hydrochloride 1 g tablet, 56**

| 9060W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 61.27 | 38.80 | Avandamet [GK] |

**rosiglitazone 4 mg + metformin hydrochloride 1 g tablet, 56**

| 9062Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 86.71 | 38.80 | Avandamet [GK] |

**rosiglitazone 4 mg + metformin hydrochloride 500 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9061X NP | 1 | 5 | .. | 85.30 | 38.80 | Avandamet [GK] |

## ▪ SAXAGLIPTIN + METFORMIN

**Note** This fixed dose combination tablet is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor

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

**Authority required (STREAMLINED)**

***6333***

Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Authority required (STREAMLINED)**

***6335***

Diabetes mellitus type 2

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and saxagliptin.

**Authority required (STREAMLINED)**

***6344***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10048W NP | 1 | 5 | .. | 59.29 | 38.80 | Kombiglyze XR 2.5/1000 [AP] |

**saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10055F NP | 1 | 5 | .. | 57.13 | 38.80 | Kombiglyze XR 5/500 [AP] |

**saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10051B NP | 1 | 5 | .. | 57.88 | 38.80 | Kombiglyze XR 5/1000 [AP] |

## ▪ SITAGLIPTIN + METFORMIN

**Note** This fixed dose combination tablet is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor

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

**Authority required (STREAMLINED)**

***6333***

Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Authority required (STREAMLINED)**

***6334***

Diabetes mellitus type 2

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and sitagliptin.

**Authority required (STREAMLINED)**

***6344***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**Authority required (STREAMLINED)**

***6443***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28**

| 10089B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 57.88 | 38.80 | Janumet XR [MK] |

**sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56**

| 9449H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 57.88 | 38.80 | Janumet [MK] |

**sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56**

| 9451K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 59.29 | 38.80 | Janumet [MK] |

**sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56**

| 10090C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 59.29 | 38.80 | Janumet XR [MK] |

**sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56**

| 9450J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 58.88 | 38.80 | Janumet [MK] |

## ▪ VILDAGLIPTIN + METFORMIN

**Note** This fixed dose combination tablet is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6333***

Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Authority required (STREAMLINED)**

***6357***

Diabetes mellitus type 2

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and vildagliptin.

**Authority required (STREAMLINED)**

***6344***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5474D NP | 1 | 5 | .. | 58.43 | 38.80 | Galvumet 50/500 [NV] |

**vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5475E NP | 1 | 5 | .. | 59.51 | 38.80 | Galvumet 50/850 [NV] |

**vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5476F NP | 1 | 5 | .. | 59.95 | 38.80 | Galvumet 50/1000 [NV] |

*Alpha glucosidase inhibitors*

## ▪ ACARBOSE

**acarbose 50 mg tablet, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8188Y NP | 1 | 5 | .. | 30.59 | 31.80 | [a] Acarbose Mylan [AF]<br>[a] GLYBOSAY [RW] | [a] Glucobay 50 [BN] |

**acarbose 100 mg tablet, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8189B NP | 1 | 5 | .. | 38.71 | 38.80 | [a] Acarbose Mylan [AF]<br>[a] GLYBOSAY [RW] | [a] Glucobay 100 [BN] |

*Thiazolidinediones*

## ▪ PIOGLITAZONE

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a glucagon-like peptide-1 or an SGLT2 inhibitor.

**Authority required (STREAMLINED)**

***4363***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR
- Patient must not have tolerated a combination of metformin and a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Authority required (STREAMLINED)**

***4388***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Authority required (STREAMLINED)**

***4364***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**pioglitazone 30 mg tablet, 28**

| 8695P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 23.04 | 24.25 | [a] Acpio 30 [RF]<br>[a] Actos [TK]<br>[a] Chem mart Pioglitazone [CH]<br>[a] Pioglitazone Sandoz [SZ]<br>[a] Terry White Chemists Pioglitazone [TW] | [a] Actaze [RW]<br>[a] APOTEX-Pioglitazone [TX]<br>[a] Pioglitazone AN [EA]<br>[a] Prioten 30 [DO]<br>[a] Vexazone [AF] |

**pioglitazone 45 mg tablet, 28**

| 8696Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 26.62 | 27.83 | [a] Acpio 45 [RF]<br>[a] Actos [TK]<br>[a] Chem mart Pioglitazone [CH]<br>[a] Pioglitazone Sandoz [SZ]<br>[a] Prioten 45 [DO]<br>[a] Vexazone [AF] | [a] Actaze [RW]<br>[a] APOTEX-Pioglitazone [TX]<br>[a] Pioglitazone AN [EA]<br>[a] Pizaccord [RA]<br>[a] Terry White Chemists Pioglitazone [TW] |

**pioglitazone 15 mg tablet, 28**

| 8694N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 18.85 | 20.06 | [a] Acpio 15 [RF]<br>[a] Actos [TK]<br>[a] Chem mart Pioglitazone [CH]<br>[a] Pioglitazone Sandoz [SZ]<br>[a] Prioten 15 [DO]<br>[a] Vexazone [AF] | [a] Actaze [RW]<br>[a] APOTEX-Pioglitazone [TX]<br>[a] Pioglitazone AN [EA]<br>[a] Pizaccord [RA]<br>[a] Terry White Chemists Pioglitazone [TW] |

*Dipeptidyl peptidase 4 (DPP-4) inhibitors*

## ▪ ALOGLIPTIN

**Note** Alogliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

**Authority required (STREAMLINED)**

***4349***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with alogliptin.

**alogliptin 25 mg tablet, 28**

| 2986E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 58.76 | 38.80 | Nesina [TK] |

**alogliptin 12.5 mg tablet, 28**

| 2933J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 58.76 | 38.80 | Nesina [TK] |

**alogliptin 6.25 mg tablet, 28**

| 2944Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 58.76 | 38.80 | Nesina [TK] |

## ▪ LINAGLIPTIN

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

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

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**Authority required (STREAMLINED)**

***6346***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Authority required (STREAMLINED)**

***6363***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

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**Authority required (STREAMLINED)**

***6376***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like

peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**linagliptin 5 mg tablet, 30**

| 3387G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 59.61 | 38.80 | Trajenta [BY] |

## ▪ SAXAGLIPTIN

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6346***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Authority required (STREAMLINED)**

***6363***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**saxagliptin 2.5 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10128C NP | 1 | 5 | .. | 56.38 | 38.80 | Onglyza [AP] |

**saxagliptin 5 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8983T NP | 1 | 5 | .. | 56.38 | 38.80 | Onglyza [AP] |

## ▪ SITAGLIPTIN

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

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

**Authority required (STREAMLINED)**

***6346***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Authority required (STREAMLINED)**

***6363***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**Authority required (STREAMLINED)**

***6376***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**sitagliptin 25 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9180E NP | 1 | 5 | .. | 56.38 | 38.80 | Januvia [MK] |

**sitagliptin 50 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9181F NP | 1 | 5 | .. | 56.38 | 38.80 | Januvia [MK] |

**sitagliptin 100 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9182G NP | 1 | 5 | .. | 56.38 | 38.80 | Januvia [MK] |

## ▪ VILDAGLIPTIN

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6346***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Authority required (STREAMLINED)**

***6363***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**vildagliptin 50 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3415R NP | 1 | 5 | .. | 59.61 | 38.80 | Galvus [NV] |

*Glucagon-like peptide-1 (GLP-1) analogues*

## ▪ EXENATIDE

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), an insulin or an SGLT2 inhibitor.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***6519***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR
- Patient must not have tolerated a combination of metformin and a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Authority required (STREAMLINED)**

***6505***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**

- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**exenatide 2 mg/dose injection: modified release, 4 injection devices**

10888C

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 130.91 | 38.80 | Bydureon [AP] |

## ▪ EXENATIDE

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or an SGLT2 inhibitor.

**Authority required (STREAMLINED)**

***5500***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR
- Patient must not have tolerated a combination of metformin and a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Authority required (STREAMLINED)**

***5478***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Authority required (STREAMLINED)**

***5469***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- The treatment must be in combination with metformin unless contraindicated or not tolerated, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**exenatide 10 microgram/dose injection, 60 doses**

| 3424F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 89.54 | 38.80 | Byetta 10 microgram [AP] |

**exenatide 5 microgram/dose injection, 60 doses**

| 3423E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 66.00 | 38.80 | Byetta 5 microgram [AP] |

*Sodium-glucose co-transporter 2 (SGLT2) inhibitors*

## ▪ DAPAGLIFLOZIN

**Note Continuing Therapy Only:**

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

**Note** This drug is not PBS subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

***4983***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Authority required (STREAMLINED)**

***4991***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Authority required (STREAMLINED)**

***5629***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**dapagliflozin 10 mg tablet, 28**

10011X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 58.27 | 38.80 | Forxiga [AP] |

NP

## ▪ EMPAGLIFLOZIN

**Note Continuing Therapy Only:**

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

**Note** This drug is not PBS subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

***5629***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**

- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

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**Authority required (STREAMLINED)**

***4983***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Authority required (STREAMLINED)**

***4991***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**empagliflozin 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10206E NP | 1 | 5 | .. | 61.64 | 38.80 | Jardiance [BY] |

**empagliflozin 25 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10202Y NP | 1 | 5 | .. | 61.64 | 38.80 | Jardiance [BY] |

# VITAMINS

## VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO

*Vitamin D and analogues*

### CALCITRIOL

**Authority required (STREAMLINED)**
***5401***
Hypocalcaemia
**Clinical criteria:**
- The condition must be due to renal disease.

**Authority required (STREAMLINED)**
***5255***
Hypoparathyroidism
**Authority required (STREAMLINED)**
***5089***
Hypophosphataemic rickets
**Authority required (STREAMLINED)**
***5114***
Vitamin D-resistant rickets
**Authority required (STREAMLINED)**
***5402***
Established osteoporosis
**Clinical criteria:**
- Patient must have fracture due to minimal trauma.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.
A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**calcitriol 0.25 microgram capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2502Q NP | 1 | 3 | .. | 27.21 | 28.42 | [a] APO-Calcitriol [TX]<br>[a] Calcitriol AN [EA]<br>[a] Sical [AF] | [a] Calciprox [ER]<br>[a] Kosteo [RW] |
| | | | [B]2.29 | 29.50 | 28.42 | [a] Rocaltrol [RO] | |

## VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12

*Vitamin B1, plain*

### THIAMINE

**Authority required (STREAMLINED)**
***5139***
Thiamine deficiency
**Clinical criteria:**
- The treatment must be for prophylaxis.

**Population criteria:**
- Patient must be an Aboriginal or a Torres Strait Islander person.

**thiamine hydrochloride 100 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1070H NP | 1 | 2 | .. | 14.98 | 16.19 | Betavit [PP] |

# MINERAL SUPPLEMENTS

## CALCIUM

*Calcium*

## ▪ CALCIUM

**Authority required (STREAMLINED)**

***4586***

Hyperphosphataemia

**Clinical criteria:**

- The condition must be associated with chronic renal failure.

**CALCIUM Tablet (chewable) 500 mg (as carbonate), 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3116B NP | 4 | 1 | .. | *29.67 | 30.88 | [a] Cal-500 [PP] | [a] Cal-Sup [IA] |

**CALCIUM Tablet 600 mg (as carbonate), 240**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3117C NP | 1 | 1 | .. | 24.12 | 25.33 | Calci-Tab 600 [AE] |

## POTASSIUM

*Potassium*

## ▪ POTASSIUM CHLORIDE

**Note** For item codes 2642C and 1841X, pharmaceutical benefits that have the form tablet 600 mg (sustained release) are equivalent for the purposes of substitution.

**potassium chloride 600 mg (potassium 8 mmol) modified release tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2642C NP | 2 | 1 | .. | *19.27 | 20.48 | [a] Duro-K [NM] |
| | | | [B]3.00 | *22.27 | 20.48 | [a] Slow-K [NV] |

**potassium chloride 600 mg (potassium 8 mmol) modified release tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1841X NP | 1 | 1 | .. | 19.26 | 20.47 | [a] Span-K [AS] |

## ▪ POTASSIUM CHLORIDE + POTASSIUM BICARBONATE + POTASSIUM CARBONATE

**potassium chloride 595 mg + potassium bicarbonate 384 mg + potassium carbonate 152 mg effervescent tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3012M NP | 1 | 1 | .. | 18.67 | 19.88 | Chlorvescent [AS] |

## OTHER MINERAL SUPPLEMENTS

*Magnesium*

## ▪ MAGNESIUM ASPARTATE DIHYDRATE

**Authority required (STREAMLINED)**

***5506***

Hypomagnesaemia

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**Authority required (STREAMLINED)**

***5466***

Chronic renal disease

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**magnesium aspartate dihydrate 500 mg (equivalent to 37.4 mg of magnesium) tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5146W NP | 1 | 5 | .. | 17.11 | 18.32 | MagMin (PBS) [BB] | Mag-Sup [PP] |

# ▪ ANABOLIC AGENTS FOR SYSTEMIC USE

## ANABOLIC STEROIDS

*Estren derivatives*

## ▪ NANDROLONE DECANOATE

**Note** Monotherapy for the treatment of osteoporosis does not exclude calcium supplementation.

**Authority required**

Osteoporosis

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The treatment must be where other treatment has failed and where specialist advice confirms that this is the only suitable treatment option for the patient.

Specialist advice need only be obtained for the first authority approval.

**Authority required**

Osteoporosis

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The treatment must be where other treatment is not tolerated and where specialist advice confirms that this is the only suitable treatment option for the patient.

Specialist advice need only be obtained for the first authority approval.

**Authority required**

Osteoporosis

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The treatment must be where other treatment is contraindicated and where specialist advice confirms that this is the only suitable treatment option for the patient.

Specialist advice need only be obtained for the first authority approval.

**Authority required**

Patients receiving this drug as a pharmaceutical benefit prior to 1 February 2004

**Authority required**

Patients on long-term treatment with corticosteroids

**nandrolone decanoate 50 mg/mL injection, 1 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1671Y | 1 | 7 | .. | 23.29 | 24.50 | Deca-Durabolin [AS] |

## OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

### OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

*Amino acids and derivatives*

### BETAINE

**Authority required**

Homocystinuria

**Clinical criteria:**

- The treatment must be as adjunctive therapy to current standard care, **AND**
- The condition must be treated by or in consultation with a metabolic physician.

The name of the specialist must be included in the authority application.

**betaine 1 g/g powder for oral liquid, 180 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10119N | ‡1 | 5 | .. | 565.87 | 38.80 | Cystadane [EU] |

*Various alimentary tract and metabolism products*

### SAPROPTERIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Hyperphenylalaninaemia

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency, **AND**
- Patient must have previously been issued with an authority prescription for this drug; OR
- Patient must have accessed non-PBS-subsidised treatment prior to 1 May 2014.

Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

The authority application must be made in writing.

**sapropterin dihydrochloride 100 mg soluble tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10087X | 6 | 5 | .. | *5309.53 | 38.80 | Kuvan [IO] |

## ▪ SAPROPTERIN

**Note** Patients will be eligible for a maximum of one script as initial therapy to enable their response to treatment with sapropterin to be assessed.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Hyperphenylalaninaemia

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency.

Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

The authority application must be made in writing.

**sapropterin dihydrochloride 100 mg soluble tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10086W | 6 | .. | .. | *5309.53 | 38.80 | Kuvan [IO] |

# ▪ BLOOD AND BLOOD FORMING ORGANS

# ▪ ANTITHROMBOTIC AGENTS

## ANTITHROMBOTIC AGENTS

*Vitamin K antagonists*

## ▪ WARFARIN

**Caution** The listed brands have NOT been shown to be bioequivalent and should not be interchanged.

**warfarin sodium 1 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2843P NP | 1 | 2 | .. | 16.05 | 17.26 | Coumadin [QA] | Marevan [FM] |

**warfarin sodium 5 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2211J NP | 1 | 2 | .. | 17.38 | 18.59 | Coumadin [QA] | Marevan [FM] |

**warfarin sodium 2 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2209G NP | 1 | 2 | .. | 16.33 | 17.54 | Coumadin [QA] |

**warfarin sodium 3 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2844Q NP | 1 | 2 | .. | 16.27 | 17.48 | Marevan [FM] |

*Heparin group*

## ▪ DALTEPARIN SODIUM

**dalteparin sodium 12 500 anti-Xa units/0.5 mL injection, 10 x 0.5 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5445N NP | 1 | 1 | .. | 114.10 | 38.80 | Fragmin [PF] |

**dalteparin sodium 10 000 anti-Xa units/mL injection, 10 x 1 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8269F NP | 1 | 1 | .. | 84.13 | 38.80 | Fragmin [PF] |

**dalteparin sodium 5000 anti-Xa units/0.2 mL injection, 10 x 0.2 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2816F NP | 2 | .. | .. | *99.55 | 38.80 | Fragmin [PF] |

**dalteparin sodium 2500 anti-Xa units/0.2 mL injection, 10 x 0.2 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8603T NP | 2 | .. | .. | *95.99 | 38.80 | Fragmin [PF] |

**dalteparin sodium 7500 anti-Xa units/0.75 mL injection, 10 x 0.75 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8271H NP | 1 | 1 | .. | 64.60 | 38.80 | Fragmin [PF] |

## ▪ DALTEPARIN SODIUM

**Restricted benefit**

Haemodialysis

**dalteparin sodium 12 500 anti-Xa units/0.5 mL injection, 10 x 0.5 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1296F NP | 2 | 3 | .. | *218.03 | 38.80 | Fragmin [PF] |

**dalteparin sodium 10 000 anti-Xa units/mL injection, 10 x 1 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1229Q NP | 2 | 3 | .. | *157.17 | 38.80 | Fragmin [PF] |

**dalteparin sodium 5000 anti-Xa units/0.2 mL injection, 10 x 0.2 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8642W NP | 2 | 3 | .. | *99.55 | 38.80 | Fragmin [PF] |

**dalteparin sodium 2500 anti-Xa units/0.2 mL injection, 10 x 0.2 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8641T NP | 2 | 3 | .. | *95.99 | 38.80 | Fragmin [PF] |

**dalteparin sodium 7500 anti-Xa units/0.75 mL injection, 10 x 0.75 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8643X NP | 2 | 3 | .. | *118.11 | 38.80 | Fragmin [PF] |

## ▪ DALTEPARIN SODIUM

**Note** No applications for increased maximum quantities will be authorised.

**Restricted benefit**

Symptomatic venous thromboembolism

Treatment Phase: Management

**Clinical criteria:**

- Patient must have a solid tumour(s).

**dalteparin sodium 12 500 anti-Xa units/0.5 mL injection, 10 x 0.5 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8958L NP | 3 | 5 | .. | *324.64 | 38.80 | Fragmin [PF] |

**DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium-porcine mucous) Injection 15,000 units (anti-Xa) in 0.6 mL single dose pre-filled syringe, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8959M NP | 3 | 5 | .. | *388.57 | 38.80 | Fragmin [PF] |

**dalteparin sodium 10 000 anti-Xa units/mL injection, 10 x 1 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8957K NP | 3 | 5 | .. | *231.58 | 38.80 | Fragmin [PF] |

**DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium-porcine mucous) Injection 18,000 units (anti-Xa) in 0.72 mL single dose pre-filled syringe, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8960N NP | 3 | 5 | .. | *465.34 | 38.80 | Fragmin [PF] |

**dalteparin sodium 7500 anti-Xa units/0.75 mL injection, 10 x 0.75 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8956J NP | 3 | 5 | .. | *171.61 | 38.80 | Fragmin [PF] |

## ▪ ENOXAPARIN SODIUM

**enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8263X NP | 1 | 1 | .. | 83.88 | 38.80 | Clexane [SW] |

**enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8510X NP | 2 | .. | .. | *99.55 | 38.80 | Clexane [SW] |

**enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8558K NP | 2 | .. | .. | *95.99 | 38.80 | Clexane [SW] |

**enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8262W NP | 1 | 1 | .. | 74.35 | 38.80 | Clexane [SW] |

**enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8264Y NP | 1 | 1 | .. | 99.75 | 38.80 | Clexane [SW] |

## ▪ ENOXAPARIN SODIUM

**Restricted benefit**

Haemodialysis

**enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5434B NP | 2 | 3 | .. | *156.67 | 38.80 | Clexane [SW] |

**enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8639Q NP | 2 | 3 | .. | *99.55 | 38.80 | Clexane [SW] |

**enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8716R NP | 2 | 3 | .. | *95.99 | 38.80 | Clexane [SW] |

**enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8640R NP | 2 | 3 | .. | *137.61 | 38.80 | Clexane [SW] |

**enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5435C NP | 2 | 3 | .. | *188.41 | 38.80 | Clexane [SW] |

## ▪ HEPARIN SODIUM

**heparin sodium 5000 units/5 mL injection, 50 x 5 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1463B NP | 1 | 5 | .. | 72.69 | 38.80 | Pfizer Australia Pty Ltd [PF] |

**heparin sodium 35 000 units/35 mL injection, 35 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1076P NP | 12 | 5 | .. | *354.67 | 38.80 | Hospira Pty Limited [PF] |

**heparin sodium 5000 units/0.2 mL injection, 5 x 0.2 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1466E NP | 1 | 5 | .. | 23.76 | 24.97 | Hospira Pty Limited [PF] |

## ▪ NADROPARIN

**nadroparin calcium 3800 anti-Xa international units/0.4 mL injection, 2 x 0.4 mL syringes**

| 10685J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 10 | .. | .. | *82.55 | 38.80 | Fraxiparine [AS] |

**nadroparin calcium 1900 anti-Xa international units/0.2 mL injection, 2 x 0.2 mL syringes**

| 10735B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 10 | .. | .. | *46.85 | 38.80 | Fraxiparine [AS] |

**nadroparin calcium 7600 anti-Xa international units/0.8 mL injection, 2 x 0.8 mL syringes**

| 10734Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 5 | 1 | .. | *82.60 | 38.80 | Fraxiparine [AS] |

**nadroparin calcium 9500 anti-Xa international units/mL injection, 2 x 1 mL syringes**

| 10702G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 5 | 1 | .. | *100.50 | 38.80 | Fraxiparine [AS] |

**nadroparin calcium 5700 anti-Xa international units/0.6 mL injection, 2 x 0.6 mL syringes**

| 10716B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 10 | .. | .. | *118.35 | 38.80 | Fraxiparine [AS] |

**nadroparin calcium 15 200 anti-Xa international units/0.8 mL injection, 2 x 0.8 mL syringes**

| 10725L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 5 | 1 | .. | *154.10 | 38.80 | Fraxiparine Forte [AS] |

**nadroparin calcium 11 400 anti-Xa international units/0.6 mL injection, 2 x 0.6 mL syringes**

| 10706L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 5 | 1 | .. | *118.35 | 38.80 | Fraxiparine Forte [AS] |

**nadroparin calcium 2850 anti-Xa international units/0.3 mL injection, 2 x 0.3 mL syringes**

| 10686K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 10 | .. | .. | *64.75 | 38.80 | Fraxiparine [AS] |

**nadroparin calcium 19 000 anti-Xa international units/mL injection, 2 x 1 mL syringes**

| 10707M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 5 | 1 | .. | *189.85 | 38.80 | Fraxiparine Forte [AS] |

## ▪ NADROPARIN

**Restricted benefit**

Haemodialysis

**nadroparin calcium 3800 anti-Xa international units/0.4 mL injection, 2 x 0.4 mL syringes**

| 10717C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 10 | 3 | .. | *82.55 | 38.80 | Fraxiparine [AS] |

**nadroparin calcium 1900 anti-Xa international units/0.2 mL injection, 2 x 0.2 mL syringes**

| 10687L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 10 | 3 | .. | *46.85 | 38.80 | Fraxiparine [AS] |

**nadroparin calcium 7600 anti-Xa international units/0.8 mL injection, 2 x 0.8 mL syringes**

| 10740G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 10 | 3 | .. | *154.05 | 38.80 | Fraxiparine [AS] |

**nadroparin calcium 9500 anti-Xa international units/mL injection, 2 x 1 mL syringes**

| 10733X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 10 | 3 | .. | *189.85 | 38.80 | Fraxiparine [AS] |

**nadroparin calcium 5700 anti-Xa international units/0.6 mL injection, 2 x 0.6 mL syringes**

| 10718D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 10 | 3 | .. | *118.35 | 38.80 | Fraxiparine [AS] |

**nadroparin calcium 2850 anti-Xa international units/0.3 mL injection, 2 x 0.3 mL syringes**

| 10701F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 10 | 3 | .. | *64.75 | 38.80 | Fraxiparine [AS] |

*Platelet aggregation inhibitors excl. heparin*

## ▪ ABCIXIMAB

**Authority required (STREAMLINED)**

***4942***

Coronary artery disease

**Treatment criteria:**

- Patient must be undergoing percutaneous coronary balloon angioplasty.

**Authority required (STREAMLINED)**

***4943***

Coronary artery disease

**Treatment criteria:**

- Patient must be undergoing percutaneous coronary atherectomy.

**Authority required (STREAMLINED)**

***4915***

Coronary artery disease

**Treatment criteria:**

- Patient must be undergoing percutaneous coronary stent placement.

**abciximab 10 mg/5 mL injection, 5 mL vial**

| 8048N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | .. | .. | *1376.14 | 38.80 | ReoPro [JC] |

## ▪ ASPIRIN

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**aspirin 300 mg effervescent tablet, 96**

| 1010E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 12.61 | 13.82 | Solprin [RC] |

## ▪ ASPIRIN

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**aspirin 100 mg tablet, 112**

| 8202Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 12.93 | 14.14 | Spren 100 [OW] |

## ▪ CLOPIDOGREL

**Note** Not for prophylaxis of deep vein thrombosis or peripheral arterial disease.

**Note** Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

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

**Authority required (STREAMLINED)**

***4166***

Acute coronary syndrome (myocardial infarction or unstable angina)

**Clinical criteria:**

- The treatment must be in combination with aspirin.

**Authority required (STREAMLINED)**

***4165***

Cardiac stent insertion

**Clinical criteria:**

- The treatment must be in combination with aspirin, **AND**
- The treatment must follow insertion of a cardiac stent.

**clopidogrel 75 mg tablet, 28**

| 2275R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.18 | 16.39 | [a] Clopidogrel-GA [EA]<br>[a] Plidogrel [RF] | [a] Clovix 75 [RW] |

**clopidogrel 75 mg tablet, 28**

| 9317J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.18 | 16.39 | [a] APO-Clopidogrel [TX] | [a] Blooms the Chemist Clopidogrel [IB] |
| | | | | | | [a] Chem mart Clopidogrel [CH] | [a] Clopidogrel AN [EA] |
| | | | | | | [a] Clopidogrel Winthrop [WA] | [a] Iscover [AV] |
| | | | | | | [a] Piax [AF] | [a] Plavix [SW] |
| | | | | | | [a] Terry White Chemists Clopidogrel [TW] | |

## ▪ CLOPIDOGREL

**Note** Not for prophylaxis of deep vein thrombosis or peripheral arterial disease.

**Note** Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg, clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

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

**Authority required (STREAMLINED)**

***5517***

Prevention of recurrence of myocardial infarction or unstable angina

**Clinical criteria:**

- Patient must have a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin.

**Authority required (STREAMLINED)**

***5524***

Prevention of recurrence of myocardial infarction or unstable angina

**Clinical criteria:**

- Patient must be in one whom low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding.

**Authority required (STREAMLINED)**

***5525***

Prevention of recurrence of myocardial infarction or unstable angina

**Clinical criteria:**

- Patient must have a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or non-steroidal anti-inflammatory drugs (NSAIDs).

**Authority required (STREAMLINED)**

***5459***

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

**Clinical criteria:**

- Patient must have a history of symptomatic cerebrovascular ischaemic episodes while on therapy with low-dose aspirin.

**Authority required (STREAMLINED)**

***5436***

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

**Clinical criteria:**

- Patient must be in one whom low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding.

**Authority required (STREAMLINED)**

***5508***

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

**Clinical criteria:**

- Patient must have a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or non-steroidal anti-inflammatory drugs (NSAIDs).

**clopidogrel 75 mg tablet, 28**

| 5436D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.18 | 16.39 | [a] Clopidogrel-DRLA [RZ] |

**clopidogrel 75 mg tablet, 28**

| 8358X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.18 | 16.39 | [a] APO-Clopidogrel [TX] | [a] Blooms the Chemist Clopidogrel [IB] |
| | | | | | | [a] Chem mart Clopidogrel [CH] | [a] Clopidogrel AN [EA] |
| | | | | | | [a] Clopidogrel RBX [RA] | [a] Clopidogrel Sandoz [SZ] |
| | | | | | | [a] Clopidogrel Winthrop [WA] | [a] Iscover [AV] |
| | | | | | | [a] Piax [AF] | [a] Plavicor 75 [CR] |
| | | | | | | [a] Plavix [SW] | [a] Terry White Chemists Clopidogrel [TW] |

**clopidogrel 75 mg tablet, 28**

| 9354H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.18 | 16.39 | [a] Clopidogrel-GA [EA]<br>[a] Clovix 75 [RW] | [a] Clopidogrel GH [GQ]<br>[a] Plidogrel [RF] |

## ▪ CLOPIDOGREL + ASPIRIN

**Note** Not for prophylaxis of deep vein thrombosis or peripheral arterial disease.

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

**Authority required (STREAMLINED)**

***5488***

Acute coronary syndrome (myocardial infarction or unstable angina)

**Authority required (STREAMLINED)**

***5443***

Cardiac stent insertion

**Clinical criteria:**

- The treatment must follow insertion of a cardiac stent.

**Authority required (STREAMLINED)**

***5517***

Prevention of recurrence of myocardial infarction or unstable angina

**Clinical criteria:**

- Patient must have a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin.

**Note** Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg, clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

**clopidogrel 75 mg + aspirin 100 mg tablet, 30**

| 9296G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.47 | 16.68 | [a] APO-Clopidogrel/Aspirin 75/100 [TX]<br>[a] Clopidogrel/Aspirin Actavis 75/100 [EA]<br>[a] Clopidogrel Winthrop plus aspirin [WA]<br>[a] DuoCover [AV]<br>[a] Piax Plus Aspirin [AF] | [a] Chem mart Clopidogrel/Aspirin 75/100 [CH]<br>[a] Clopidogrel/Aspirin Sandoz 75/100 [SZ]<br>[a] CoPlavix [SW]<br>[a] DuoPlidogrel [GZ]<br>[a] Terry White Chemists Clopidogrel/Aspirin 75/100 [TW] |

## ▪ DIPYRIDAMOLE

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

**Restricted benefit**

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

**Clinical criteria:**

- The treatment must be as adjunctive therapy with low-dose aspirin.

**Restricted benefit**

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

**Clinical criteria:**

- Patient must be one in whom low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding.

**Restricted benefit**

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

**Clinical criteria:**

- Patient must have a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or non-steroidal anti-inflammatory drugs (NSAIDs).

**dipyridamole 200 mg modified release capsule, 60**

| 8335Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 36.32 | 37.53 | Persantin SR [BY] |

## ▪ DIPYRIDAMOLE + ASPIRIN

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

**Restricted benefit**

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

**dipyridamole 200 mg + aspirin 25 mg modified release capsule, 60**

8382E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 33.57 | 34.78 | [a] Asasantin SR [BY] | [a] Diasp SR [RW] |

NP

## ▪ EPTIFIBATIDE

**Authority required (STREAMLINED)**

***6435***

Coronary artery disease

**Treatment criteria:**

- Patient must be undergoing non-urgent percutaneous intervention with intracoronary stenting.

**eptifibatide 75 mg/100 mL injection, 100 mL vial**

8684C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | .. | .. | *963.40 | 38.80 | Integrilin [MK] |

**eptifibatide 20 mg/10 mL injection, 10 mL vial**

8683B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *238.91 | 38.80 | Integrilin [MK] |

## ▪ PRASUGREL

**Note Shared Care Model**:

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

**Authority required (STREAMLINED)**

***6454***

Acute coronary syndrome (myocardial infarction or unstable angina)

**Clinical criteria:**

- The treatment must be managed by percutaneous coronary intervention in combination with aspirin.

**prasugrel 5 mg tablet, 28**

9495R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 88.83 | 38.80 | Effient [LY] |

NP

**prasugrel 10 mg tablet, 28**

9496T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 97.46 | 38.80 | Effient [LY] |

NP

## ▪ TICAGRELOR

**Note Shared Care Model**:

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

**Authority required (STREAMLINED)**

***5746***

Acute coronary syndrome (myocardial infarction or unstable angina)

**Clinical criteria:**

- The treatment must be in combination with aspirin.

**TICAGRELOR Tablet 90 mg, 56**

1418P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 140.71 | 38.80 | Brilinta [AP] |

NP

## ▪ TIROFIBAN

**Note Shared Care Model**:

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

**Authority required (STREAMLINED)**

***5782***

High risk of unstable angina

**Clinical criteria:**

- Patient must have new transient or persistent ST-T ischaemic changes, **AND**
- Patient must have pain lasting longer than 20 minutes.

**Authority required (STREAMLINED)**

***5809***

High risk of unstable angina

**Clinical criteria:**

- Patient must have new transient or persistent ST-T ischaemic changes, **AND**
- Patient must have repetitive episodes of angina at rest or during minimal exercise in the previous 12 hours.

**Authority required (STREAMLINED)**

***5691***

Non-Q-wave myocardial infarction

**tirofiban 12.5 mg/50 mL injection, 50 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8350L NP | 1 | 2 | .. | 231.00 | 38.80 | [a] Aggrastat [AS] | [a] Tirofiban AC [JO] |

*Enzymes*

## ▪ RETEPLASE

**Note Shared Care Model**:

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

**Restricted benefit**

Acute myocardial infarction

**Clinical criteria:**

- The treatment must be administered within 6 hours of the onset of attack.

**reteplase 10 units (17.4 mg) injection [2 x 10 unit vials] (&) inert substance diluent [2 x 10 mL syringes], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8253J NP | ‡1 | .. | .. | 1965.61 | 38.80 | Rapilysin 10 U [GN] |

## ▪ TENECTEPLASE

**Note Shared Care Model**:

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

**Restricted benefit**

Acute myocardial infarction

**Clinical criteria:**

- The treatment must be administrated within 12 hours of onset of attack.

**tenecteplase 8000 units (40 mg) injection [1 vial] (&) inert substance diluent [8 mL syringe], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8526R NP | 1 | .. | .. | 1861.19 | 38.80 | Metalyse [BY] |

**tenecteplase 10 000 units (50 mg) injection [1 vial] (&) inert substance diluent [10 mL syringe], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8527T NP | 1 | .. | .. | 1955.88 | 38.80 | Metalyse [BY] |

*Direct thrombin inhibitors*

## ▪ BIVALIRUDIN

**Authority required (STREAMLINED)**

***4919***

Coronary artery disease

**Treatment criteria:**

- Patient must be undergoing percutaneous coronary intervention.

**bivalirudin 250 mg injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8844L | 1 | .. | .. | 533.18 | 38.80 | [a] Angiomax [XM] | [a] Bivalirudin APOTEX [TX] |

## ▪ DABIGATRAN

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

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

**Note Shared Care Model**:

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

**Authority required (STREAMLINED)**

***4402***

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total hip replacement.

**Clinical criteria:**

- Patient must require up to 30 days supply to complete a course of treatment.

**dabigatran etexilate 110 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9321N NP | 1 | .. | .. | 88.38 | 38.80 | Pradaxa [BY] |

**dabigatran etexilate 75 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9320M NP | 1 | .. | .. | 109.79 | 38.80 | Pradaxa [BY] |

## ▪ DABIGATRAN

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

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

**Note Shared Care Model**:

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

**Authority required (STREAMLINED)**

***4369***

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total hip replacement.

**Clinical criteria:**

- Patient must require up to 20 days supply to complete a course of treatment.

**dabigatran etexilate 75 mg capsule, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9318K NP | 2 | 1 | .. | *43.99 | 38.80 | Pradaxa [BY] |

**dabigatran etexilate 110 mg capsule, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9319L NP | 2 | 1 | .. | *36.85 | 38.06 | Pradaxa [BY] |

## ▪ DABIGATRAN

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

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

**Note Shared Care Model**:

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

**Authority required (STREAMLINED)**

***4381***

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total knee replacement.

**Clinical criteria:**

- Patient must require up to 10 days of therapy.

**dabigatran etexilate 75 mg capsule, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9322P NP | 2 | .. | .. | *43.99 | 38.80 | Pradaxa [BY] |

**dabigatran etexilate 110 mg capsule, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9323Q NP | 2 | .. | .. | *36.85 | 38.06 | Pradaxa [BY] |

## ▪ DABIGATRAN

**Note Shared Care Model**:

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

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

**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**
***4269***
Prevention of stroke or systemic embolism
**Clinical criteria:**
- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:
(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
(ii) age 75 years or older;
(iii) hypertension;
(iv) diabetes mellitus;
(v) heart failure and/or left ventricular ejection fraction 35% or less.

**dabigatran etexilate 110 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2753X NP | 1 | 5 | .. | 88.38 | 38.80 | Pradaxa [BY] |

**dabigatran etexilate 150 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2769R NP | 1 | 5 | .. | 88.38 | 38.80 | Pradaxa [BY] |

*Direct factor Xa inhibitors*

## ▪ APIXABAN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***4402***
Prevention of venous thromboembolism
**Treatment criteria:**
- Patient must be undergoing total hip replacement.

**Clinical criteria:**
- Patient must require up to 30 days supply to complete a course of treatment.

**apixaban 2.5 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5061J NP | 1 | .. | .. | 92.92 | 38.80 | Eliquis [BQ] |

## ▪ APIXABAN

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**
***4098***
Deep vein thrombosis
Treatment Phase: Initial treatment
**Clinical criteria:**
- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

**Authority required (STREAMLINED)**
***5098***
Pulmonary embolism
Treatment Phase: Initial treatment
**Clinical criteria:**
- Patient must have confirmed acute symptomatic pulmonary embolism.

**apixaban 5 mg tablets, 28**

10414D NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 49.28 | 38.80 | Eliquis [BQ] |

## ▪ APIXABAN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***4382***
Prevention of venous thromboembolism
**Treatment criteria:**
- Patient must be undergoing total knee replacement.

**Clinical criteria:**
- Patient must require up to 15 days of therapy.

**Authority required (STREAMLINED)**
***4409***
Prevention of venous thromboembolism
**Treatment criteria:**
- Patient must be undergoing total hip replacement.

**Clinical criteria:**
- Patient must require up to 15 days supply to complete a course of treatment.

**apixaban 2.5 mg tablet, 30**

5054B NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 52.01 | 38.80 | Eliquis [BQ] |

## ▪ APIXABAN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***4381***
Prevention of venous thromboembolism
**Treatment criteria:**
- Patient must be undergoing total knee replacement.

**Clinical criteria:**
- Patient must require up to 10 days of therapy.

**Authority required (STREAMLINED)**
***4359***
Prevention of venous thromboembolism
**Treatment criteria:**
- Patient must be undergoing total hip replacement.

**Clinical criteria:**
- Patient must require up to 10 days supply to complete a course of treatment.

**apixaban 2.5 mg tablet, 20**

5500L NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 38.37 | 38.80 | Eliquis [BQ] |

## ▪ APIXABAN

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**
***4269***
Prevention of stroke or systemic embolism
**Clinical criteria:**

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***4132***

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a history of venous thromboembolism.

**apixaban 2.5 mg tablet, 60**

2744K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 92.92 | 38.80 | Eliquis [BQ] |

NP

## ▪ APIXABAN

**Note Shared Care Model**:

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

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

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

**Authority required (STREAMLINED)**

***4269***

Prevention of stroke or systemic embolism

**Clinical criteria:**

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***4099***

Deep vein thrombosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

**Authority required (STREAMLINED)**

***5083***

Pulmonary embolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic pulmonary embolism.

**apixaban 5 mg tablet, 60**

2735Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 92.92 | 38.80 | Eliquis [BQ] |

NP

## ▪ RIVAROXABAN

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

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

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4369***

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total hip replacement.

**Clinical criteria:**

- Patient must require up to 20 days supply to complete a course of treatment.

**rivaroxaban 10 mg tablet, 10**

| 9465E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 38.26 | 38.80 | Xarelto [BN] |

## ▪ RIVAROXABAN

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

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

**Note Shared Care Model**:

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

**Authority required (STREAMLINED)**

***4402***

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total hip replacement.

**Clinical criteria:**

- Patient must require up to 30 days supply to complete a course of treatment.

**RIVAROXABAN Tablet 10 mg, 30**

| 9467G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 92.60 | 38.80 | Xarelto [BN] |

**rivaroxaban 10 mg tablet, 15**

| 9466F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 51.85 | 38.80 | Xarelto [BN] |

## ▪ RIVAROXABAN

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

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

**Note Shared Care Model**:

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

**Authority required (STREAMLINED)**

***4381***

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total knee replacement.

**Clinical criteria:**

- Patient must require up to 10 days of therapy.

**rivaroxaban 10 mg tablet, 10**

| 9468H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 38.26 | 38.80 | Xarelto [BN] |

## ▪ RIVAROXABAN

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

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

**Note Shared Care Model**:

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

**Authority required (STREAMLINED)**

***4382***

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total knee replacement.

**Clinical criteria:**

- Patient must require up to 15 days of therapy.

**rivaroxaban 10 mg tablet, 15**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9469J NP | 1 | .. | .. | 51.85 | 38.80 | Xarelto [BN] |

## ▪ RIVAROXABAN

**Note Shared Care Model**:

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

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***4269***

Prevention of stroke or systemic embolism

**Clinical criteria:**

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

**rivaroxaban 15 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2691P NP | 1 | 5 | .. | 87.17 | 38.80 | Xarelto [BN] |

## ▪ RIVAROXABAN

**Note Shared Care Model**:

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

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

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

**Authority required (STREAMLINED)**

***4098***

Deep vein thrombosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

**Authority required (STREAMLINED)**

***4260***

Pulmonary embolism

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic pulmonary embolism.

**Note** Special Pricing Arrangements apply.

**rivaroxaban 15 mg tablet, 42**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2160Q NP | 1 | .. | .. | 125.21 | 38.80 | Xarelto [BN] |

## ▪ RIVAROXABAN

**Note Shared Care Model**:

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

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

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

**Authority required (STREAMLINED)**

***4099***

Deep vein thrombosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

**Authority required (STREAMLINED)**

***4132***

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a history of venous thromboembolism.

**Authority required (STREAMLINED)**

***4268***

Pulmonary embolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic pulmonary embolism.

**Note** Special Pricing Arrangements apply.

---

**Authority required (STREAMLINED)**

***4269***

Prevention of stroke or systemic embolism

**Clinical criteria:**

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

**Note** Special Pricing Arrangements apply.

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**rivaroxaban 20 mg tablet, 28**

| 2268J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 87.17 | 38.80 | Xarelto [BN] |

*Other antithrombotic agents*

## ▪ FONDAPARINUX

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

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

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

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**Authority required (STREAMLINED)**

***5781***

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing major hip surgery.

**Authority required (STREAMLINED)**

***5808***

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total knee replacement.

**FONDAPARINUX SODIUM Injection 2.5 mg in 0.5 mL single dose pre-filled syringe, 2**

| 8775W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3.5 | .. | .. | *127.04 | 38.80 | Arixtra [AS] |

# ▪ ANTIHEMORRHAGICS

## ANTIFIBRINOLYTICS

*Amino acids*

### ▪ TRANEXAMIC ACID

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

**tranexamic acid 500 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2180R NP | 1 | 2 | .. | 43.61 | 38.80 | [a] APO-Tranexamic Acid [TX] | [a] Cyklokapron [PF] |

## ▪ ANTIANEMIC PREPARATIONS

### IRON PREPARATIONS

*Iron bivalent, oral preparations*

### ▪ FERROUS FUMARATE

**Restricted benefit**
For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**ferrous fumarate 200 mg (equivalent to 65.7 mg of elemental iron) tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8985X NP | 1 | 1 | .. | 17.76 | 18.97 | Ferro-tab [AE] |

### ▪ FERROUS SULFATE

**ferrous sulfate 30 mg/mL (equivalent to 6 mg/mL elemental iron) oral liquid, 250 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8815Y NP | ‡1 | 2 | .. | 21.77 | 22.98 | Ferro-Liquid [AE] |

*Iron, parenteral preparations*

### ▪ IRON

**iron (as ferric carboxymaltose) 500 mg/10 mL injection, 1 x 10 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10104T NP | 2 | 1 | .. | *307.49 | 38.80 | ferinject [VL] |

### ▪ IRON POLYMALTOSE

**iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2593L NP | 1 | .. | .. | 23.69 | 24.90 | Ferrosig [SI] |

### ▪ IRON POLYMALTOSE

**Authority required (STREAMLINED)**
***4302***
Iron deficiency anaemia
**Treatment criteria:**

- Patient must be undergoing chronic haemodialysis.

**iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2805P NP | 1 | 5 | .. | 23.69 | 24.90 | Ferrosig [SI] |

### ▪ IRON SUCROSE

**iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10229J NP | 1 | .. | .. | 40.06 | 38.80 | Venofer [AS] |

### ▪ IRON SUCROSE

**Authority required (STREAMLINED)**
***4302***
Iron deficiency anaemia
**Treatment criteria:**

- Patient must be undergoing chronic haemodialysis.

**iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8807M NP | 1 | 5 | .. | 40.06 | 38.80 | Venofer [AS] |

*Iron in combination with folic acid*

## ▪ FERROUS FUMARATE + FOLIC ACID

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**ferrous fumarate 310 mg (equivalent to 100 mg elemental iron) + folic acid 350 microgram tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9011G NP | 1 | 1 | .. | 18.78 | 19.99 | Ferro-f-tab [AE] |

## VITAMIN B12 AND FOLIC ACID

*Vitamin B12 (cyanocobalamin and analogues)*

## ▪ HYDROXOCOBALAMIN

**Note** One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin $B_{12}$ deficiencies.

**Note** Pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as acetate) in 1 mL and pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as chloride) in 1 mL are equivalent for the purposes of substitution.

**Restricted benefit**

Pernicious anaemia

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Proven vitamin B12 deficiencies other than pernicious anaemia

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Anaemias associated with vitamin B12 deficiency

**Clinical criteria:**

- Patient must have had a gastrectomy, **AND**
- The treatment must be for prophylaxis.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2162T NP | 1 | .. | .. | 15.36 | 16.57 | [a] Vita-B12 [GH] |

**hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9048F NP | 1 | .. | .. | 15.36 | 16.57 | [a] Hydroxo-B12 [AS] | [a] Neo-B12 [PF] |

*Folic acid and derivatives*

## ▪ FOLIC ACID

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**folic acid 500 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2958Q NP | 2 | .. | .. | *15.15 | 16.36 | [a] Foltabs 500 [PP] | [a] Megafol 0.5 [AF] |

## ▪ FOLIC ACID

**Note** The 5 mg strength tablet should be used in malabsorption states only.

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**folic acid 5 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1437P NP | 2 | 1 | .. | *17.37 | 18.58 | Megafol 5 [AF] |

# BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

## BLOOD AND RELATED PRODUCTS

*Blood substitutes and plasma protein fractions*

### PENTASTARCH + SODIUM CHLORIDE

**HYDROXYETHYL STARCH 130/0.4 I.V. infusion 30 g per 500 mL, 500 mL, 1**

| 9487H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | .. | .. | *44.17 | 38.80 | Voluven 6% [PK] |

### SUCCINYLATED GELATIN

**succinylated gelatin 20 g/500 mL injection, 500 mL bag**

| 8444K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | .. | .. | *44.17 | 38.80 | Gelofusine [BR] |

# OTHER HEMATOLOGICAL AGENTS

## OTHER HEMATOLOGICAL AGENTS

*Drugs used in hereditary angioedema*

### ICATIBANT

**Note** Icatibant should be provided in the framework of a comprehensive hereditary angioedema prophylaxis program and an emergency Action Plan including training in recognition of the symptoms of hereditary angioedema and the self-administration of icatibant. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au)

**Authority required**

Anticipated emergency treatment of an acute attack of hereditary angioedema

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have confirmed diagnosis of C1-esterase inhibitor deficiency, **AND**
- Patient must have been assessed to be at significant risk of an acute attack of hereditary angioedema, **AND**
- The condition must be assessed by a clinical immunologist; OR
- The condition must be assessed by a respiratory physician; OR
- The condition must be assessed by a specialist allergist; OR
- The condition must be assessed by a general physician experienced in the management of patients with hereditary angioedema.

The name of the specialist consulted must be provided at the time of application for initial supply.

The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.

**Authority required**

Anticipated emergency treatment of an acute attack of hereditary angioedema

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug.

**ICATIBANT Injection 30 mg (as acetate) in 3 mL single use pre-filled syringe, 1**

| 1976B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 2574.52 | 38.80 | Firazyr [ZI] |

# CARDIOVASCULAR SYSTEM

# CARDIAC THERAPY

## CARDIAC GLYCOSIDES

*Digitalis glycosides*

### DIGOXIN

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

**digoxin 50 microgram/mL oral liquid, 60 mL**

| 3164M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 3 | .. | *41.29 | 38.80 | Lanoxin [QA] |

**digoxin 62.5 microgram tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2605D NP | 1 | 1 | .. | 14.57 | 15.78 | [a] Sigmaxin-PG [FM] |
| | | | [B]2.56 | 17.13 | 15.78 | [a] Lanoxin-PG [QA] |

**digoxin 250 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1322N NP | 1 | 1 | .. | 14.82 | 16.03 | [a] Sigmaxin [FM] |
| | | | [B]2.56 | 17.38 | 16.03 | [a] Lanoxin [QA] |

## ANTIARRHYTHMICS, CLASS I AND III

### *Antiarrhythmics, class Ia*

### ▪ DISOPYRAMIDE

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

**disopyramide 100 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2923W NP | 1 | 5 | .. | 29.85 | 31.06 | Rythmodan [SW] |

### *Antiarrhythmics, class Ib*

### ▪ LIGNOCAINE

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

**lignocaine hydrochloride anhydrous 500 mg/5 mL injection, 10 x 5 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2876J NP | 1 | .. | .. | 30.23 | 31.44 | Xylocard 500 [AS] |

### *Antiarrhythmics, class Ic*

### ▪ FLECAINIDE

**Caution** Flecainide acetate should be avoided in patients with poor cardiac function.

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

**Restricted benefit**
Serious supra-ventricular cardiac arrhythmias

**Restricted benefit**
Serious ventricular cardiac arrhythmias

**Clinical criteria:**

- The treatment must be initiated in a hospital.

**flecainide acetate 100 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1090J NP | 1 | 5 | .. | 39.45 | 38.80 | [a] Flecainide Sandoz [SZ]<br>[a] Tambocor [IA] | [a] Flecatab [AF] |

**flecainide acetate 50 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1088G NP | 1 | 5 | .. | 33.97 | 35.18 | [a] Flecainide Sandoz [SZ] | [a] Tambocor [IA] |

### *Antiarrhythmics, class III*

### ▪ AMIODARONE

**Note** This drug has been reported to cause frequent and potentially serious toxicity.

**Note** Regular monitoring of hepatic and thyroid function is recommended.

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

**Restricted benefit**
Severe cardiac arrhythmias

**amiodarone hydrochloride 100 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2344J NP | 1 | 5 | .. | 15.44 | 16.65 | [a] Aratac 100 [AF] | [a] Cordarone X 100 [SW] |

**amiodarone hydrochloride 200 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2343H NP | 1 | 5 | .. | 18.83 | 20.04 | [a] Amiodarone Sandoz [SZ]<br>[a] Cordarone X 200 [SW]<br>[a] Rithmik 200 [RW] | [a] Aratac 200 [AF]<br>[a] GenRx Amiodarone [GX] |

## ▪ SOTALOL

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

**Restricted benefit**
Severe cardiac arrhythmias

**sotalol hydrochloride 160 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2043M NP | 1 | 5 | .. | 18.00 | 19.21 | [a] APO-Sotalol [TX]<br>[a] Solavert [RF] | [a] Cardol [AF]<br>[a] Sotalol Sandoz [SZ] |
| | | | [B]4.33 | 22.33 | 19.21 | [a] Sotacor [RW] | |

**sotalol hydrochloride 80 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8398B NP | 1 | 5 | .. | 14.30 | 15.51 | [a] APO-Sotalol [TX]<br>[a] Solavert [RF] | [a] Cardol [AF]<br>[a] Sotalol Sandoz [SZ] |
| | | | [B]4.33 | 18.63 | 15.51 | [a] Sotacor [RW] | |

# CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES

*Adrenergic and dopaminergic agents*

## ▪ ADRENALINE

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1016L NP | 1 | 1 | .. | 22.58 | 23.79 | Link Medical Products Pty Ltd [LM] |

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5004J DP | 1 | .. | .. | 22.58 | 23.79 | Link Medical Products Pty Ltd [LM] |

## ▪ ADRENALINE

**Caution** EpiPen and Anapen products have different administration techniques and should not be prescribed to the same patient without training in their use.

**Note** The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au.)

**Note** Authority approvals will be limited to a maximum quantity of 2 auto-injectors (Anapen or EpiPen) at any one time.

**Note** No applications for repeats will be authorised.

**Authority required**
Acute allergic reaction with anaphylaxis
Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment
**Clinical criteria:**

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.

The name of the specialist consulted must be provided at the time of application for initial supply.

**Authority required**
Acute allergic reaction with anaphylaxis
Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment
**Clinical criteria:**

- Patient must have been discharged from hospital or an emergency department after treatment with adrenaline for acute allergic reaction with anaphylaxis.

**Authority required**

Acute allergic reaction with anaphylaxis

Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug.

**adrenaline 300 microgram/0.3 mL injection, 1 dose**

| 8698T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 97.10 | 38.80 | EpiPen [AL] |

**adrenaline 150 microgram/0.3 mL injection, 1 dose**

| 8697R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 97.10 | 38.80 | EpiPen Jr. [AL] |

## VASODILATORS USED IN CARDIAC DISEASES

*Organic nitrates*

### ▪ GLYCERYL TRINITRATE

**glyceryl trinitrate 600 microgram sublingual tablet, 100**

| 1459T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 18.40 | 19.61 | Nitrostat [PF]<br>[a] Lycinate [RF] |
| | | | [B]2.56 | 20.96 | 19.61 | [a] Anginine Stabilised [RW] |

**glyceryl trinitrate 600 microgram sublingual tablet, 100**

| 5108W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | ‡1 | .. | .. | 18.40 | 19.61 | Nitrostat [PF]<br>[a] Lycinate [RF] |
| | | | [B]2.56 | 20.96 | 19.61 | [a] Anginine Stabilised [RW] |

**glyceryl trinitrate 5 mg/24 hours patch, 30**

| 1515R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 27.31 | 28.52 | Transiderm-Nitro 25 [SZ] |

**glyceryl trinitrate 5 mg/24 hours patch, 30**

| 8010N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 27.31 | 28.52 | Nitro-Dur 5 [MK] |

**glyceryl trinitrate 5 mg/24 hours patch, 30**

| 8027L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 27.31 | 28.52 | Minitran 5 [IA] |

**glyceryl trinitrate 15 mg/24 hours patch, 30**

| 8026K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 32.36 | 33.57 | Nitro-Dur 15 [MK] |

**glyceryl trinitrate 15 mg/24 hours patch, 30**

| 8119H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 32.36 | 33.57 | Minitran 15 [IA] |

**glyceryl trinitrate 10 mg/24 hours patch, 30**

| 1516T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 32.36 | 33.57 | Transiderm-Nitro 50 [SZ] |

**glyceryl trinitrate 10 mg/24 hours patch, 30**

| 8011P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 32.36 | 33.57 | Nitro-Dur 10 [MK] |

**glyceryl trinitrate 10 mg/24 hours patch, 30**

| 8028M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 32.36 | 33.57 | Minitran 10 [IA] |

**glyceryl trinitrate 300 microgram sublingual tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11027J NP | ‡1 | 5 | .. | 18.40 | 19.61 | Nitrostat [PF] |

**glyceryl trinitrate 300 microgram sublingual tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11051P DP | ‡1 | .. | .. | 18.40 | 19.61 | Nitrostat [PF] |

## ▪ GLYCERYL TRINITRATE

**Note** The spray should not be inhaled.

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8171C NP | ‡1 | 5 | .. | 23.01 | 24.22 | Nitrolingual Pumpspray [SW] |

## ▪ ISOSORBIDE DINITRATE

**isosorbide dinitrate 5 mg sublingual tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2588F NP | 2 | 2 | .. | *18.17 | 19.38 | Isordil Sublingual [RW] |

## ▪ ISOSORBIDE MONONITRATE

**isosorbide mononitrate 60 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1558B NP | 1 | 5 | .. | 14.77 | 15.98 | [a] Chem mart Isosorbide Mononitrate [CH] | [a] Duride [AF] |
| | | | | | | [a] GenRx Isosorbide Mononitrate [GX] | [a] Isomonit [SZ] |
| | | | | | | [a] Isosorbide AN [EA] | [a] Terry White Chemists Isosorbide Mononitrate [TW] |
| | | | [B]2.48 | 17.25 | 15.98 | [a] Monodur 60 mg [PM] | |
| | | | [B]3.37 | 18.14 | 15.98 | [a] Imdur Durule [AP] | |

**isosorbide mononitrate 120 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8273K NP | 1 | 5 | .. | 18.41 | 19.62 | [a] Monodur 120 mg [PM] |
| | | | [B]3.37 | 21.78 | 19.62 | [a] Imdur 120 mg [AP] |

*Other vasodilators used in cardiac diseases*

## ▪ NICORANDIL

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

**nicorandil 20 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8229D NP | ‡1 | 5 | .. | 30.56 | 31.77 | [a] Ikorel [SW] | [a] Ikotab [QA] |

**nicorandil 10 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8228C NP | ‡1 | 5 | .. | 25.07 | 26.28 | [a] Ikorel [SW] | [a] Ikotab [QA] |

## ▪ PERHEXILINE

**Note** Regular monitoring of drug serum levels is recommended.

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

**Authority required (STREAMLINED)**

***5592***

Angina

**Clinical criteria:**

- The condition must not be responding to other therapy.

**perhexiline maleate 100 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1822X NP | 1 | 5 | .. | 59.62 | 38.80 | Pexsig [QA] |

## OTHER CARDIAC PREPARATIONS

*Other cardiac preparations*

### ▪ IVABRADINE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***4979***

Chronic heart failure

**Clinical criteria:**

- Patient must be symptomatic with NYHA classes II or III, **AND**
- Patient must be in sinus rhythm, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%, **AND**
- Patient must have a resting heart rate at or above 77 bpm at the time ivabradine treatment is initiated, **AND**
- Patient must receive concomitant optimal standard chronic heart failure treatment, which must include the maximum tolerated dose of a beta-blocker, unless contraindicated or not tolerated.

Resting heart rate should be measured by ECG or echocardiography, after 5 minutes rest.

The ECG or echocardiography, result must be documented in the patient's medical records when treatment is initiated.

**ivabradine 5 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10012Y NP | 1 | 5 | .. | 56.25 | 38.80 | Coralan [SE] |

**ivabradine 7.5 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2960T NP | 1 | 5 | .. | 56.25 | 38.80 | Coralan [SE] |

# ▪ ANTIHYPERTENSIVES

## ANTIADRENERGIC AGENTS, CENTRALLY ACTING

*Methyldopa*

### ▪ METHYLDOPA

**methyldopa 250 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1629R NP | 1 | 5 | .. | 19.89 | 21.10 | [a] Hydopa [AF] |
| | | | [B]3.08 | 22.97 | 21.10 | [a] Aldomet [AS] |

*Imidazoline receptor agonists*

### ▪ CLONIDINE

**clonidine hydrochloride 100 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3145M NP | 1 | 5 | .. | 26.67 | 27.88 | [a] APO-Clonidine [TX] | [a] Catapres 100 [BY] |

**clonidine hydrochloride 150 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3141H NP | 1 | 5 | .. | 32.62 | 33.83 | Catapres [BY] |

### ▪ MOXONIDINE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- Patient must be receiving concurrent antihypertensive therapy.

**moxonidine 200 microgram tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9019Q NP | 1 | 5 | .. | 21.92 | 23.13 | Physiotens [GO] |

**moxonidine 400 microgram tablet, 30**

| 9020R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 29.56 | 30.77 | Physiotens [GO] |

## ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING

*Alpha-adrenoreceptor antagonists*

### ▪ PRAZOSIN

**prazosin 5 mg tablet, 100**

| 1478T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 21.65 | 22.86 | [a] APO-Prazosin [TX]<br>[a] Minipress [PF] | [a] Chem mart Prazosin [CH]<br>[a] Terry White Chemists Prazosin [TW] |

**prazosin 2 mg tablet, 100**

| 1480X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.97 | 18.18 | [a] APO-Prazosin [TX]<br>[a] Minipress [PF] | [a] Chem mart Prazosin [CH]<br>[a] Terry White Chemists Prazosin [TW] |

**prazosin 1 mg tablet, 100**

| 1479W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.22 | 16.43 | [a] APO-Prazosin [TX]<br>[a] Minipress [PF] | [a] Chem mart Prazosin [CH]<br>[a] Terry White Chemists Prazosin [TW] |

## ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON

*Hydrazinophthalazine derivatives*

### ▪ HYDRALAZINE

**hydralazine hydrochloride 50 mg tablet, 100**

| 1639G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | .. | *21.51 | 22.72 | Alphapress 50 [AF] |

**hydralazine hydrochloride 25 mg tablet, 100**

| 1640H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | .. | *20.07 | 21.28 | Alphapress 25 [AF] |

*Pyrimidine derivatives*

### ▪ MINOXIDIL

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Severe refractory hypertension

**Clinical criteria:**

- The treatment must be initiated by a consultant physician.

**minoxidil 10 mg tablet, 100**

| 2313R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 57.59 | 38.80 | Loniten [PF] |

# ▪ DIURETICS

## LOW-CEILING DIURETICS, THIAZIDES

*Thiazides, plain*

### ▪ HYDROCHLOROTHIAZIDE

**hydrochlorothiazide 25 mg tablet, 100**

| 1484D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 23.34 | 24.55 | Dithiazide [PL] |

## LOW-CEILING DIURETICS, EXCL. THIAZIDES

*Sulfonamides, plain*

## ▪ CHLORTHALIDONE

**chlorthalidone 25 mg tablet, 50**

| 1585K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 1 | .. | *20.29 | 21.50 | Hygroton 25 [GH] |

## ▪ INDAPAMIDE

**indapamide hemihydrate 1.5 mg modified release tablet, 90**

| 8532C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 18.80 | 20.01 | [a] APO-Indapamide SR [TX] | [a] Chem mart Indapamide SR [CH] |
| | | | | | | [a] INDAPAMIDE AN SR [EA] | [a] Odaplix SR [AF] |
| | | | | | | [a] Tenaxil SR [RW] | [a] Terry White Chemists Indapamide SR [TW] |
| | | | [B]4.38 | 23.18 | 20.01 | [a] Natrilix SR [SE] | |

**indapamide hemihydrate 2.5 mg tablet, 90**

| 2436F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 16.37 | 17.58 | [a] Dapa-Tabs [AF] | [a] GenRx Indapamide [GX] |
| | | | | | | [a] Indapamide AN [EA] | [a] Indapamide Sandoz [SZ] |
| | | | | | | [a] Insig [RW] | |
| | | | [B]4.39 | 20.76 | 17.58 | [a] Natrilix [SE] | |

## HIGH-CEILING DIURETICS

*Sulfonamides, plain*

## ▪ FRUSEMIDE

**frusemide 10 mg/mL oral liquid, 30 mL**

| 2411X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 3 | .. | 27.11 | 28.32 | Lasix [SW] |

**frusemide 500 mg tablet, 50**

| 2415D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 3 | .. | 18.92 | 20.13 | Urex-Forte [RW] |

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

| 2413B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 13.24 | 14.45 | [a] Frusemide-Claris [AE] | [a] Frusemide Sandoz [SZ] |
| | | | | | | [a] Lasix [SW] | |

**frusemide 40 mg tablet, 100**

| 2412Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 12.77 | 13.98 | Urex [RW] | |
| | | | | | | [a] APO-Frusemide [TX] | [a] Chem mart Frusemide [CH] |
| | | | | | | [a] Frusax [ER] | [a] Frusemide RBX [RA] |
| | | | | | | [a] Frusemide Sandoz [SZ] | [a] FUROSEMIDE AN [EA] |
| | | | | | | [a] Terry White Chemists Frusemide [TW] | [a] Uremide [AF] |
| | | | [B]1.85 | 14.62 | 13.98 | [a] Lasix [SW] | |

## ▪ FRUSEMIDE

**Note** For item codes 2414C and 1810G, pharmaceutical benefits that have the form tablet 20 mg are equivalent for the purposes of substitution.

**frusemide 20 mg tablet, 100**

| 2414C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 12.77 | 13.98 | [a] APO-Frusemide [TX] | [a] Chem mart Frusemide [CH] |
| | | | | | | [a] Frusemide RBX [RA] | [a] FUROSEMIDE AN [EA] |
| | | | | | | [a] Terry White Chemists Frusemide [TW] | |

**frusemide 20 mg tablet, 50**

| 1810G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 1 | .. | *12.77 | 13.98 | [a] Urex-M [RW] |
| | | | [B]1.46 | *14.23 | 13.98 | [a] Lasix-M [SW] |

*Aryloxyacetic acid derivatives*

## ▪ ETHACRYNIC ACID

**Restricted benefit**

Patients hypersensitive to other oral diuretics

**ethacrynic acid 25 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8748K NP | 2 | 1 | .. | *175.93 | 38.80 | Edecrin [FK] |

# POTASSIUM-SPARING AGENTS

*Aldosterone antagonists*

## ▪ EPLERENONE

**Caution** Serum electrolytes should be checked regularly

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***4937***

Heart failure with a left ventricular ejection fraction of 40% or less

**Clinical criteria:**

- The condition must occur within 3 to 14 days following an acute myocardial infarction, **AND**
- The treatment must be commenced within 14 days of an acute myocardial infarction.

The date of the acute myocardial infarction and the date of initiation of treatment with this drug must be documented in the patient's medical records when PBS-subsidised treatment is initiated

**eplerenone 25 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8879H NP | 1 | 5 | .. | 88.24 | 38.80 | [a] Eplerenone AN [EA]<br>[a] Inpler [AF] | [a] ESPLER [RW]<br>[a] Inspra [PF] |

**eplerenone 50 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8880J NP | 1 | 5 | .. | 88.24 | 38.80 | [a] Eplerenone AN [EA]<br>[a] Inpler [AF] | [a] ESPLER [RW]<br>[a] Inspra [PF] |

## ▪ SPIRONOLACTONE

**Caution** Serum electrolytes should be checked regularly

Appropriate contraceptive measures should be taken by women of child-bearing age in whom spironolactone therapy has been initiated.

**spironolactone 100 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2340E NP | 1 | 5 | .. | 30.83 | 32.04 | [a] Spiractin 100 [AF] |
| | | | [B]7.49 | 38.32 | 32.04 | [a] Aldactone [PF] |

**spironolactone 25 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2339D NP | 1 | 5 | .. | 16.11 | 17.32 | [a] Spiractin 25 [AF] |
| | | | [B]7.50 | 23.61 | 17.32 | [a] Aldactone [PF] |

# DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION

*Low-ceiling diuretics and potassium-sparing agents*

## ▪ AMILORIDE + HYDROCHLOROTHIAZIDE

**Caution** Serum electrolytes should be checked regularly.

**amiloride hydrochloride 5 mg + hydrochlorothiazide 50 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1486F NP | 2 | 1 | .. | *17.25 | 18.46 | Moduretic [AS] |

## ▪ HYDROCHLOROTHIAZIDE + TRIAMTERENE

**Caution** Serum electrolytes should be checked regularly.

**hydrochlorothiazide 25 mg + triamterene 50 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1280J NP | 1 | 1 | .. | 16.72 | 17.93 | Hydrene 25/50 [AF] |

# ▪ PERIPHERAL VASODILATORS

## PERIPHERAL VASODILATORS

*Other peripheral vasodilators*

### ▪ PHENOXYBENZAMINE

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Phaeochromocytoma

**Restricted benefit**

Neurogenic urinary retention

**phenoxybenzamine hydrochloride 10 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1862B NP | 1 | 5 | .. | 1103.27 | 38.80 | Dibenyline [GH] |

**phenoxybenzamine hydrochloride 10 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9286R NP | 1 | 5 | .. | 1103.27 | 38.80 | Dibenzyline [BZ] |

**phenoxybenzamine hydrochloride 10 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1166J NP | 3 | 5 | .. | *997.75 | 38.80 | Amdipharm Mercury (Australia) Pty Limited [GH] |

# ▪ BETA BLOCKING AGENTS

## BETA BLOCKING AGENTS

*Beta blocking agents, non-selective*

### ▪ OXPRENOLOL

**oxprenolol hydrochloride 40 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2961W NP | 1 | 5 | .. | 46.54 | 38.80 | Corbeton 40 [AF] |

### ▪ PINDOLOL

**pindolol 5 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3062E NP | 1 | 5 | .. | 31.97 | 33.18 | Barbloc 5 [AF] |

### ▪ PROPRANOLOL

**propranolol hydrochloride 160 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2899N NP | 1 | 5 | .. | 17.81 | 19.02 | Deralin 160 [AF] |

**propranolol hydrochloride 10 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2565B NP | 1 | 5 | .. | 13.84 | 15.05 | [a] APO-Propranolol [TX] |
| | | | [B]2.99 | 16.83 | 15.05 | [a] Deralin 10 [AF] |
| | | | [B]3.75 | 17.59 | 15.05 | [a] Inderal [AP] |

**propranolol hydrochloride 40 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2566C NP | 1 | 5 | .. | 14.11 | 15.32 | [a] APO-Propranolol [TX] |
| | | | [B]2.99 | 17.10 | 15.32 | [a] Deralin 40 [AF] |
| | | | [B]3.75 | 17.86 | 15.32 | [a] Inderal [AP] |

*Beta blocking agents, selective*

## ▪ ATENOLOL

### atenolol 50 mg tablet, 30

1081X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 12.23 | 13.44 | [a] APO-Atenolol [TX]<br>[a] Atenolol AN [EA]<br>[a] Atenolol GH [GQ]<br>[a] Atenolol Sandoz [SZ]<br>[a] Noten [AF]<br>[a] Tensig [RW] | [a] Atenolol Amneal [EF]<br>[a] Atenolol-GA [ED]<br>[a] Atenolol RBX [RA]<br>[a] Chem mart Atenolol [CH]<br>[a] Tenolten 50 [DO]<br>[a] Terry White Chemists Atenolol [TW] |
| | | [B]2.44 | 14.67 | 13.44 | [a] Tenormin [AP] | |

## ▪ ATENOLOL

**Restricted benefit**

For a patient who is unable to take a solid dose form of atenolol.

### atenolol 50 mg/10 mL oral liquid, 300 mL

2243C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 29.37 | 30.58 | Atenolol-AFT [AE] |

## ▪ BISOPROLOL

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Moderate to severe heart failure

**Clinical criteria:**

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

### bisoprolol fumarate 10 mg tablet, 28

8606Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 21.63 | 22.84 | [a] APO-Bisoprolol [TX]<br>[a] Bicard 10 [RW]<br>[a] Bisoprolol AN [EA]<br>[a] Bisoprolol Sandoz [SZ]<br>[a] Chem mart Bisoprolol [CH] | [a] Beprol 10 [DO]<br>[a] Biso 10 [ED]<br>[a] Bisoprolol generichealth [GQ]<br>[a] Bispro 10 [AF]<br>[a] Terry White Chemists Bisoprolol [TW] |
| | | [B]5.88 | 27.51 | 22.84 | [a] Bicor [AL] | |

### bisoprolol fumarate 2.5 mg tablet, 28

8604W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 17.84 | 19.05 | [a] APO-Bisoprolol [TX]<br>[a] Bicard 2.5 [RW]<br>[a] Bisoprolol AN [EA]<br>[a] Bisoprolol Sandoz [SZ]<br>[a] Chem mart Bisoprolol [CH] | [a] Beprol 2.5 [DO]<br>[a] Biso 2.5 [ED]<br>[a] Bisoprolol generichealth [GQ]<br>[a] Bispro 2.5 [AF]<br>[a] Terry White Chemists Bisoprolol [TW] |
| | | [B]5.88 | 23.72 | 19.05 | [a] Bicor [AL] | |

### bisoprolol fumarate 5 mg tablet, 28

8605X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 19.52 | 20.73 | [a] APO-Bisoprolol [TX]<br>[a] Bicard 5 [RW]<br>[a] Bisoprolol AN [EA]<br>[a] Bisoprolol Sandoz [SZ]<br>[a] Chem mart Bisoprolol [CH] | [a] Beprol 5 [DO]<br>[a] Biso 5 [ED]<br>[a] Bisoprolol generichealth [GQ]<br>[a] Bispro 5 [AF]<br>[a] Terry White Chemists Bisoprolol [TW] |
| | | [B]5.87 | 25.39 | 20.73 | [a] Bicor [AL] | |

## ▪ METOPROLOL SUCCINATE

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Moderate to severe heart failure

**Clinical criteria:**

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

### METOPROLOL SUCCINATE Tablet 47.5 mg (controlled release), 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8733P NP | 1 | 5 | .. | 50.07 | 38.80 | [a] Metrol-XL 47.5 [RW]<br>[a] Toprol-XL 47.5 [AP] | [a] Minax XL [AF] |

### METOPROLOL SUCCINATE Tablet 23.75 mg (controlled release), 15

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8732N NP | 1 | .. | .. | 19.35 | 20.56 | [a] Metrol-XL 23.75 [RW]<br>[a] Toprol-XL 23.75 [AP] | [a] Minax XL [AF] |

### METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8735R NP | 1 | 5 | .. | 71.97 | 38.80 | [a] Metrol-XL 190 [RW]<br>[a] Toprol-XL 190 [AP] | [a] Minax XL [AF] |

### METOPROLOL SUCCINATE Tablet 95 mg (controlled release), 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8734Q NP | 1 | 5 | .. | 59.80 | 38.80 | [a] Metrol-XL 95 [RW]<br>[a] Toprol-XL 95 [AP] | [a] Minax XL [AF] |

## ▪ METOPROLOL TARTRATE

### METOPROLOL TARTRATE Tablet 100 mg, 60

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1325R NP | 1 | 5 | .. | 13.52 | 14.73 | [a] Metoprolol AN [EA]<br>[a] Mistrom [ER]<br>[b] APO-Metoprolol [TX]<br>[b] Metoprolol Sandoz [SZ]<br>[b] Minax 100 [AF] | [a] Metoprolol RBX [RA]<br><br>[b] Chem mart Metoprolol [CH]<br>[b] Metrol 100 [RW]<br>[b] Terry White Chemists Metoprolol [TW] |
| | | | [B]1.80 | 15.32 | 14.73 | [a] Lopresor 100 [NV] | |
| | | | [B]3.76 | 17.28 | 14.73 | [b] Betaloc [AP] | |

### METOPROLOL TARTRATE Tablet 50 mg, 100

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1324Q NP | 1 | 5 | .. | 12.99 | 14.20 | [a] Metoprolol AN [EA]<br>[a] Mistrom [ER]<br>[b] APO-Metoprolol [TX]<br>[b] Metoprolol Sandoz [SZ]<br>[b] Minax 50 [AF] | [a] Metoprolol RBX [RA]<br><br>[b] Chem mart Metoprolol [CH]<br>[b] Metrol 50 [RW]<br>[b] Terry White Chemists Metoprolol [TW] |
| | | | [B]1.80 | 14.79 | 14.20 | [a] Lopresor 50 [NV] | |
| | | | [B]3.76 | 16.75 | 14.20 | [b] Betaloc [AP] | |

## ▪ NEBIVOLOL

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Moderate to severe heart failure

**Clinical criteria:**

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

### nebivolol 5 mg tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9311C NP | 1 | 5 | .. | 58.17 | 38.80 | Nebilet [FK] |

### nebivolol 1.25 mg tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9316H NP | 2 | 5 | .. | *48.81 | 38.80 | Nebilet [FK] |

**nebivolol 10 mg tablet, 28**

| 9312D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 64.29 | 38.80 | Nebilet [FK] |

*Alpha and beta blocking agents*

## ▪ CARVEDILOL

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Moderate to severe heart failure

**Clinical criteria:**

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

**Restricted benefit**

Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002

**carvedilol 6.25 mg tablet, 60**

| 8256M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 19.70 | 20.91 | [a] APO-Carvedilol [TX]<br>[a] Carvedilol Sandoz [SZ]<br>[a] Dicarz [AF]<br>[a] Terry White Chemists Carvedilol 6.25 mg [TW]<br>[a] Volirop 6.25 [DO] | [a] Carvedilol AN [EA]<br>[a] Chem mart Carvedilol 6.25 mg [CH]<br>[a] Dilatrend 6.25 [RO]<br>[a] Vedilol 6.25 [RW] |

**carvedilol 25 mg tablet, 60**

| 8258P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 24.55 | 25.76 | [a] APO-Carvedilol [TX]<br>[a] Carvedilol Sandoz [SZ]<br>[a] Dicarz [AF]<br>[a] Terry White Chemists Carvedilol 25 mg [TW]<br>[a] Volirop 25 [DO] | [a] Carvedilol AN [EA]<br>[a] Chem mart Carvedilol 25 mg [CH]<br>[a] Dilatrend 25 [RO]<br>[a] Vedilol 25 [RW] |

**carvedilol 3.125 mg tablet, 30**

| 8255L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 13.48 | 14.69 | [a] APO-Carvedilol [TX]<br>[a] Chem mart Carvedilol 3.125 mg [CH]<br>[a] Vedilol 3.125 [RW] | [a] Carvedilol AN [EA]<br>[a] Terry White Chemists Carvedilol 3.125 mg [TW]<br>[a] Volirop 3.125 [DO] |

**carvedilol 12.5 mg tablet, 60**

| 8257N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 21.86 | 23.07 | [a] APO-Carvedilol [TX]<br>[a] Carvedilol Sandoz [SZ]<br>[a] Dicarz [AF]<br>[a] Terry White Chemists Carvedilol 12.5 mg [TW]<br>[a] Volirop 12.5 [DO] | [a] Carvedilol AN [EA]<br>[a] Chem mart Carvedilol 12.5 mg [CH]<br>[a] Dilatrend 12.5 [RO]<br>[a] Vedilol 12.5 [RW] |

## ▪ LABETALOL

**labetalol hydrochloride 100 mg tablet, 100**

| 1566K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 24.34 | 25.55 | [a] Presolol 100 [AF] |
| | | | [B]3.50 | 27.84 | 25.55 | [a] Trandate [QA] |

**labetalol hydrochloride 200 mg tablet, 100**

| 1567L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 24.34 | 25.55 | [a] Presolol 200 [AF] |
| | | | [B]3.50 | 27.84 | 25.55 | [a] Trandate [QA] |

# CALCIUM CHANNEL BLOCKERS

## SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS

*Dihydropyridine derivatives*

### AMLODIPINE

**amlodipine 10 mg tablet, 30**

| 2752W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 12.67 | 13.88 | [a] Amlo 10 [RW] | [a] Amlodipine Amneal [EF] |
| | | | | | | [a] Amlodipine AN [EA] | [a] Amlodipine GH [GQ] |
| | | | | | | [a] Amlodipine Sandoz [SZ] | [a] APO-Amlodipine [TX] |
| | | | | | | [a] Auro-Amlodipine 10 [DO] | [a] Blooms the Chemist Amlodipine [IB] |
| | | | | | | [a] Chem mart Amlodipine [CH] | [a] Nordip [AF] |
| | | | | | | [a] Norvapine [ED] | [a] Ozlodip [RA] |
| | | | | | | [a] Pharmacor Amlodipine [CR] | [a] Terry White Chemists Amlodipine [TW] |
| | | | [B]9.20 | 21.87 | 13.88 | [a] Norvasc [PF] | |

**amlodipine 5 mg tablet, 30**

| 2751T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 11.98 | 13.19 | [a] Amlo 5 [RW] | [a] Amlodipine Amneal [EF] |
| | | | | | | [a] Amlodipine AN [EA] | [a] Amlodipine GH [GQ] |
| | | | | | | [a] Amlodipine Sandoz [SZ] | [a] APO-Amlodipine [TX] |
| | | | | | | [a] Auro-Amlodipine 5 [DO] | [a] Blooms the Chemist Amlodipine [IB] |
| | | | | | | [a] Chem mart Amlodipine [CH] | [a] Nordip [AF] |
| | | | | | | [a] Norvapine [ED] | [a] Ozlodip [RA] |
| | | | | | | [a] Pharmacor Amlodipine [CR] | [a] Terry White Chemists Amlodipine [TW] |
| | | | [B]9.20 | 21.18 | 13.19 | [a] Norvasc [PF] | |

### FELODIPINE

**felodipine 5 mg modified release tablet, 30**

| 2366M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.12 | 16.33 | [a] Felodil XR 5 [RW] | [a] Felodur ER 5 mg [TX] |
| | | | | | | [a] Fendex ER [AF] | |
| | | | [B]2.09 | 17.21 | 16.33 | [a] Plendil ER [GX] | |

**felodipine 10 mg modified release tablet, 30**

| 2367N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 18.39 | 19.60 | [a] Felodil XR 10 [RW] | [a] Felodur ER 10 mg [TX] |
| | | | | | | [a] Fendex ER [AF] | |
| | | | [B]2.09 | 20.48 | 19.60 | [a] Plendil ER [GX] | |

**felodipine 2.5 mg modified release tablet, 30**

| 2361G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 13.90 | 15.11 | [a] Felodur ER 2.5 mg [TX] | [a] Fendex ER [AF] |
| | | | [B]2.08 | 15.98 | 15.11 | [a] Plendil ER [GX] | |

### LERCANIDIPINE

**lercanidipine hydrochloride 20 mg tablet, 28**

| 8679T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.58 | 15.79 | [a] APO-Lercanidipine [TX] | [a] Blooms the Chemist Lercanidipine [IB] |
| | | | | | | [a] Chem mart Lercanidipine [CH] | [a] Ledip [RA] |
| | | | | | | [a] Lercadip [EA] | [a] Lercan [RW] |
| | | | | | | [a] Lercanidipine GH [GQ] | [a] Lercanidipine Sandoz [SZ] |
| | | | | | | [a] Terry White Chemists Lercanidipine [TW] | [a] Zircol [AF] |
| | | | [B]2.77 | 17.35 | 15.79 | [a] Zanidip [GO] | |

**lercanidipine hydrochloride 10 mg tablet, 28**

| 8534E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 13.19 | 14.40 | [a] APO-Lercanidipine [TX] | [a] Blooms the Chemist Lercanidipine [IB] |
| | | | | | | [a] Chem mart Lercanidipine [CH] | [a] Ledip [RA] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Lercadip [EA]<br>[a] Lercanidipine GH [GQ]<br>[a] Terry White Chemists Lercanidipine [TW] | [a] Lercan [RW]<br>[a] Lercanidipine Sandoz [SZ]<br>[a] Zircol [AF] |
| | | | [B]2.76 | 15.95 | 14.40 | [a] Zanidip [GO] | |

## ▪ NIFEDIPINE

### nifedipine 20 mg modified release tablet, 30

| 8610E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.47 | 18.68 | Adalat Oros 20mg [BN] |

### nifedipine 60 mg modified release tablet, 30

| 1907J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 19.75 | 20.96 | [a] Addos XR 60 [RW]<br>[a] APO-Nifedipine XR [TX] | [a] Adefin XL 60 [AF] |
| | | | [B]2.66 | 22.41 | 20.96 | [a] Adalat Oros 60 [BN] | |

### nifedipine 20 mg tablet, 60

| 1695F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.23 | 18.44 | [a] Adefin 20 [AF] |
| | | | [B]2.29 | 19.52 | 18.44 | [a] Adalat 20 [BN] |

### nifedipine 10 mg tablet, 60

| 1694E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.08 | 17.29 | [a] Adefin 10 [AF] |
| | | | [B]1.64 | 17.72 | 17.29 | [a] Adalat 10 [BN] |

### nifedipine 30 mg modified release tablet, 30

| 1906H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.98 | 19.19 | [a] Addos XR 30 [RW]<br>[a] APO-Nifedipine XR [TX] | [a] Adefin XL 30 [AF] |
| | | | [B]2.52 | 20.50 | 19.19 | [a] Adalat Oros 30 [BN] | |

## SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS

*Phenylalkylamine derivatives*

## ▪ VERAPAMIL

**Caution** The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

### verapamil hydrochloride 240 mg modified release tablet, 30

| 1241H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 19.13 | 20.34 | [a] Cordilox SR [GT] |
| | | | [B]3.50 | 22.63 | 20.34 | [a] Isoptin SR [GO] |

### verapamil hydrochloride 180 mg modified release tablet, 30

| 2208F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.12 | 18.33 | [a] Cordilox 180 SR [GT] |
| | | | [B]3.50 | 20.62 | 18.33 | [a] Isoptin 180 SR [GO] |

### verapamil hydrochloride 40 mg tablet, 100

| 1248Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.96 | 17.17 | Anpec 40 [AF] |

### verapamil hydrochloride 80 mg tablet, 100

| 1250T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 18.56 | 19.77 | [a] Anpec 80 [AF] |
| | | | [B]3.50 | 22.06 | 19.77 | [a] Isoptin [GO] |

*Benzothiazepine derivatives*

## ▪ DILTIAZEM

**Caution** The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

### diltiazem hydrochloride 240 mg modified release capsule, 30

| 1313D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 20.18 | 21.39 | [a] Diltiazem Sandoz CD [SZ] | [a] Vasocardol CD [AV] |
| | | | [B]1.90 | 22.08 | 21.39 | [a] Cardizem CD [SW] | |

**diltiazem hydrochloride 360 mg modified release capsule, 30**

| 8480H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 23.00 | 24.21 | [a] Diltiazem Sandoz CD [SZ] | [a] Vasocardol CD [AV] |
| | | | [B]1.90 | 24.90 | 24.21 | [a] Cardizem CD [SW] | |

**diltiazem hydrochloride 180 mg modified release capsule, 30**

| 1312C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.81 | 19.02 | [a] Diltiazem Sandoz CD [SZ] | [a] Vasocardol CD [AV] |
| | | | [B]1.90 | 19.71 | 19.02 | [a] Cardizem CD [SW] | |

**diltiazem hydrochloride 60 mg tablet, 90**

| 1335G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.15 | 18.36 | [a] Diltiazem Actavis [ED]<br>[a] Diltiazem Sandoz [SZ] | [a] Diltiazem AN [EA] |
| | | | [B]1.90 | 19.05 | 18.36 | [a] Cardizem [SW] | [a] Vasocardol [AV] |

## AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

### ACE INHIBITORS, PLAIN

*ACE inhibitors, plain*

### CAPTOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**captopril 50 mg tablet, 90**

| 1149L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 20.65 | 21.86 | [a] Captopril Sandoz [SZ] |
| | | | [B]3.43 | 24.08 | 21.86 | [a] Zedace [AF] |
| | | | [B]3.90 | 24.55 | 21.86 | [a] Capoten [RW] |

**captopril 12.5 mg tablet, 90**

| 1147J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.44 | 15.65 | [a] Captopril Sandoz [SZ] |
| | | | [B]3.43 | 17.87 | 15.65 | [a] Zedace [AF] |

**captopril 25 mg tablet, 90**

| 1148K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.94 | 17.15 | [a] Captopril Sandoz [SZ] |
| | | | [B]3.43 | 19.37 | 17.15 | [a] Zedace [AF] |
| | | | [B]4.67 | 20.61 | 17.15 | [a] Capoten [RW] |

### CAPTOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Patients unable to take a solid dose form of an ACE inhibitor.

**captopril 5 mg/mL oral liquid, 95 mL**

| 8760C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 106.91 | 38.80 | Capoten [RW] |

### ENALAPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**enalapril maleate 5 mg tablet, 30**

| 1370D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 12.96 | 14.17 | [a] Acetec [AL]<br>[a] Enalapril Actavis [ED]<br>[a] Enalapril generichealth [GQ]<br>[a] Malean [RW] | [a] APO-Enalapril [TX]<br>[a] Enalapril AN [EA]<br>[a] Enalapril Sandoz [SZ] |

**enalapril maleate 10 mg tablet, 30**

| 1368B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.18 | 15.39 | [a] Acetec [AL]<br>[a] Enalapril Actavis [ED]<br>[a] Enalapril generichealth [GQ]<br>[a] Malean [RW] | [a] APO-Enalapril [TX]<br>[a] Enalapril AN [EA]<br>[a] Enalapril Sandoz [SZ] |
| | | | [B]5.36 | 19.54 | 15.39 | [a] Renitec [MK] | |

**enalapril maleate 20 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1369C NP | 1 | 5 | .. | 15.01 | 16.22 | [a] Acetec [AL]<br>[a] Enalapril Actavis [ED]<br>[a] Enalapril generichealth [GQ]<br>[a] Malean [RW] | [a] APO-Enalapril [TX]<br>[a] Enalapril AN [EA]<br>[a] Enalapril Sandoz [SZ] |
| | | | [B]5.36 | 20.37 | 16.22 | [a] Renitec 20 [MK] | |

## ▪ FOSINOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**fosinopril sodium 20 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1183G NP | 1 | 5 | .. | 17.80 | 19.01 | [a] APO-Fosinopril [TX]<br>[a] Monace 20 [AF] | [a] Fosipril 20 [RW] |

**fosinopril sodium 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1182F NP | 1 | 5 | .. | 15.58 | 16.79 | [a] APO-Fosinopril [TX]<br>[a] Monace 10 [AF] | [a] Fosipril 10 [RW] |

## ▪ LISINOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**lisinopril 20 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2458J NP | 1 | 5 | .. | 15.17 | 16.38 | [a] APO-Lisinopril [TX]<br>[a] Chem mart Lisinopril [CH]<br>[a] Lisinopril AN [EA]<br>[a] Lisinopril Sandoz [SZ]<br>[a] Zinopril 20 [AL] | [a] Auro-Lisinopril 20 [DO]<br>[a] Fibsol 20 [RW]<br>[a] Lisinopril generichealth [GQ]<br>[a] Terry White Chemists Lisinopril [TW] |
| | | | [B]3.30 | 18.47 | 16.38 | [a] Zestril [AP] | |

**lisinopril 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2456G NP | 1 | 5 | .. | 13.25 | 14.46 | [a] APO-Lisinopril [TX]<br>[a] Chem mart Lisinopril [CH]<br>[a] Lisinopril AN [EA]<br>[a] Lisinopril Sandoz [SZ]<br>[a] Zinopril 5 [AL] | [a] Auro-Lisinopril 5 [DO]<br>[a] Fibsol 5 [RW]<br>[a] Lisinopril generichealth [GQ]<br>[a] Terry White Chemists Lisinopril [TW] |
| | | | [B]3.30 | 16.55 | 14.46 | [a] Zestril [AP] | |

**lisinopril 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2457H NP | 1 | 5 | .. | 14.33 | 15.54 | [a] APO-Lisinopril [TX]<br>[a] Chem mart Lisinopril [CH]<br>[a] Lisinopril AN [EA]<br>[a] Lisinopril Sandoz [SZ]<br>[a] Zinopril 10 [AL] | [a] Auro-Lisinopril 10 [DO]<br>[a] Fibsol 10 [RW]<br>[a] Lisinopril generichealth [GQ]<br>[a] Terry White Chemists Lisinopril [TW] |
| | | | [B]3.30 | 17.63 | 15.54 | [a] Zestril [AP] | |

## ▪ PERINDOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril erbumine 2 mg tablet and pharmaceutical benefits that have the form perindopril arginine 2.5 mg tablet are equivalent for the purposes of substitution.

**perindopril arginine 2.5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9006B NP | 1 | 5 | .. | 12.63 | 13.84 | [a] APO-Perindopril Arginine [TX] | [a] PREXUM 2.5 [RW] |
| | | | [B]4.17 | 16.80 | 13.84 | [a] Coversyl 2.5mg [SE] | |

**perindopril erbumine 2 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3050M NP | 1 | 5 | .. | 12.63 | 13.84 | [a] APO-Perindopril [TX]<br>[a] Chem mart Perindopril [CH] | [a] Blooms the Chemist Perindopril [IB]<br>[a] Idaprex 2 [SZ] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Indosyl Mono 2 [RW]<br>[a] Perindopril Actavis 2 [EA]<br>[a] Terry White Chemists Perindopril [TW] | [a] Perindo [AF]<br>[a] Perindopril AN [EF] |

## ▪ PERINDOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril erbumine 4 mg tablet and pharmaceutical benefits that have the form perindopril arginine 5 mg tablet are equivalent for the purposes of substitution.

### perindopril erbumine 4 mg tablet, 30

| 3051N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 13.95 | 15.16 | [a] APO-Perindopril [TX]<br>[a] Chem mart Perindopril [CH]<br>[a] Indosyl Mono 4 [RW]<br>[a] Perindopril Actavis 4 [ED]<br>[a] Perindopril CH [EA]<br>[a] Terry White Chemists Perindopril [TW] | [a] Blooms the Chemist Perindopril [IB]<br>[a] Idaprex 4 [SZ]<br>[a] Perindo [AF]<br>[a] Perindopril AN [EF]<br>[a] Perindopril generichealth [GQ] |

### perindopril arginine 5 mg tablet, 30

| 9007C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 13.95 | 15.16 | [a] APO-Perindopril Arginine [TX] | [a] PREXUM 5 [RW] |
| | | | [B]4.15 | 18.10 | 15.16 | [a] Coversyl 5mg [SE] | |

## ▪ PERINDOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril erbumine 8 mg tablet and pharmaceutical benefits that have the form perindopril arginine 10 mg tablet are equivalent for the purposes of substitution.

### perindopril erbumine 8 mg tablet, 30

| 8704D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.47 | 16.68 | [a] APO-Perindopril [TX]<br>[a] Chem mart Perindopril [CH]<br>[a] Indosyl Mono 8 [RW]<br>[a] Perindopril Actavis 8 [ED]<br>[a] Perindopril CH [EA]<br>[a] Terry White Chemists Perindopril [TW] | [a] Blooms the Chemist Perindopril [IB]<br>[a] Idaprex 8 [SZ]<br>[a] Perindo [AF]<br>[a] Perindopril AN [EF]<br>[a] Perindopril generichealth [GQ] |

### perindopril arginine 10 mg tablet, 30

| 9008D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.47 | 16.68 | [a] APO-Perindopril Arginine [TX] | [a] PREXUM 10 [RW] |
| | | | [B]4.15 | 19.62 | 16.68 | [a] Coversyl 10mg [SE] | |

## ▪ QUINAPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

### quinapril 10 mg tablet, 30

| 1969P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.08 | 16.29 | [a] Acquin Aspen 10 [RW]<br>[a] Qpril 10 [AF] | [a] APO-Quinapril [TX] |
| | | | [B]4.20 | 19.28 | 16.29 | [a] Accupril [PF] | |

### quinapril 5 mg tablet, 30

| 1968N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.22 | 15.43 | [a] ACQUIN [RF]<br>[a] Qpril 5 [AF] | [a] Acquin Aspen 5 [RW] |
| | | | [B]4.20 | 18.42 | 15.43 | [a] Accupril [PF] | |

### quinapril 20 mg tablet, 30

| 1970Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.01 | 17.22 | [a] ACQUIN [RF]<br>[a] APO-Quinapril [TX]<br>[a] Quinapril generichealth [GQ] | [a] Acquin Aspen 20 [RW]<br>[a] Qpril 20 [AF] |
| | | | [B]4.20 | 20.21 | 17.22 | [a] Accupril [PF] | |

## ▪ RAMIPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 10 mg tablet and pharmaceutical benefits that have the form ramipril 10 mg capsule are equivalent for the purposes of substitution.

### ramipril 10 mg capsule, 30

8470T NP

| Max.Qty | Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1 | 5 | .. | 14.39 | 15.60 | [a] APO-Ramipril [TX]<br>[a] Ramace 10 mg [AV]<br>[a] Ramipril generichealth [GQ]<br>[a] Ramipril Winthrop [WA]<br>[a] Tritace 10 mg [SW]<br>[a] Vascalace Caps 10 [DO] | [a] Chem mart Ramipril [CH]<br>[a] Ramipril AN [EA]<br>[a] Ramipril Sandoz [SZ]<br>[a] Terry White Chemists Ramipril [TW]<br>[a] Tryzan Caps 10 [AF] | |

### ramipril 10 mg tablet, 30

1316G NP

| Max.Qty | Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1 | 5 | .. | 14.39 | 15.60 | [a] APO-Ramipril [TX]<br>[a] Ramipril AN [EA]<br>[a] Ramipril Winthrop [WA]<br>[a] Tritace [SW]<br>[a] Vascalace 10 [DO] | [a] Chem mart Ramipril [CH]<br>[a] Ramipril Sandoz [SZ]<br>[a] Terry White Chemists Ramipril [TW]<br>[a] Tryzan Tabs 10 [AF] | |

## ▪ RAMIPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 1.25 mg tablet and pharmaceutical benefits that have the form ramipril 1.25 mg capsule are equivalent for the purposes of substitution.

### ramipril 1.25 mg capsule, 30

9120B NP

| Max.Qty | Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1 | 5 | .. | 12.11 | 13.32 | [a] APO-Ramipril [TX]<br>[a] Terry White Chemists Ramipril [TW]<br>[a] Vascalace Caps 1.25 [DO] | [a] Chem mart Ramipril [CH]<br>[a] Tryzan Caps 1.25 [AF] | |

### ramipril 1.25 mg tablet, 30

1944H NP

| Max.Qty | Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1 | 5 | .. | 12.11 | 13.32 | [a] Ramace 1.25 mg [AV]<br>[a] Ramipril Sandoz [SZ]<br>[a] Tritace 1.25 mg [SW]<br>[a] Vascalace 1.25 [DO] | [a] Ramipril AN [EA]<br>[a] Ramipril Winthrop [WA]<br>[a] Tryzan Tabs 1.25 [AF] | |

## ▪ RAMIPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 2.5 mg tablet and pharmaceutical benefits that have the form ramipril 2.5 mg capsule are equivalent for the purposes of substitution.

### ramipril 2.5 mg tablet, 30

1945J NP

| Max.Qty | Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1 | 5 | .. | 12.58 | 13.79 | [a] APO-Ramipril [TX]<br>[a] Ramace 2.5 mg [AV]<br>[a] Ramipril Sandoz [SZ]<br>[a] Terry White Chemists Ramipril [TW]<br>[a] Tryzan Tabs 2.5 [AF] | [a] Chem mart Ramipril [CH]<br>[a] Ramipril AN [EA]<br>[a] Ramipril Winthrop [WA]<br>[a] Tritace 2.5 mg [SW]<br>[a] Vascalace 2.5 [DO] | |

### ramipril 2.5 mg capsule, 30

9121C NP

| Max.Qty | Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1 | 5 | .. | 12.58 | 13.79 | [a] APO-Ramipril [TX]<br>[a] Ramipril generichealth [GQ]<br>[a] Tryzan Caps 2.5 [AF] | [a] Chem mart Ramipril [CH]<br>[a] Terry White Chemists Ramipril [TW]<br>[a] Vascalace Caps 2.5 [DO] | |

## ▪ RAMIPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 5 mg tablet and pharmaceutical benefits that have the form ramipril 5 mg capsule are equivalent for the purposes of substitution.

**ramipril 5 mg tablet, 30**

| 1946K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 12.96 | 14.17 | [a] APO-Ramipril [TX] | [a] Chem mart Ramipril [CH] |
| | | | | | | [a] Ramace 5 mg [AV] | [a] Ramipril AN [EA] |
| | | | | | | [a] Ramipril Sandoz [SZ] | [a] Ramipril Winthrop [WA] |
| | | | | | | [a] Terry White Chemists Ramipril [TW] | [a] Tritace 5 mg [SW] |
| | | | | | | [a] Tryzan Tabs 5 [AF] | [a] Vascalace 5 [DO] |

**ramipril 5 mg capsule, 30**

| 9122D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 12.96 | 14.17 | [a] APO-Ramipril [TX] | [a] Chem mart Ramipril [CH] |
| | | | | | | [a] Ramipril generichealth [GQ] | [a] Terry White Chemists Ramipril [TW] |
| | | | | | | [a] Tryzan Caps 5 [AF] | [a] Vascalace Caps 5 [DO] |

## ▪ TRANDOLAPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**trandolapril 4 mg capsule, 28**

| 8758Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 20.08 | 21.29 | [a] Dolapril 4 [RW] | [a] Tranalpha [AF] |
| | | | [B]3.49 | 23.57 | 21.29 | [a] Gopten [GO] | |

**trandolapril 1 mg capsule, 28**

| 2792Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.06 | 16.27 | [a] Dolapril 1 [RW] | [a] Tranalpha [AF] |
| | | | [B]3.50 | 18.56 | 16.27 | [a] Gopten [GO] | |

**trandolapril 500 microgram capsule, 28**

| 2791X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 13.20 | 14.41 | [a] Dolapril 0.5 [RW] | [a] Tranalpha [AF] |
| | | | [B]3.50 | 16.70 | 14.41 | [a] Gopten [GO] | |

**trandolapril 2 mg capsule, 28**

| 2793B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.87 | 17.08 | [a] Dolapril 2 [RW] | [a] Tranalpha [AF] |
| | | | [B]3.50 | 19.37 | 17.08 | [a] Gopten [GO] | |

## ACE INHIBITORS, COMBINATIONS

*ACE inhibitors and diuretics*

## ▪ ENALAPRIL + HYDROCHLOROTHIAZIDE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**enalapril maleate 20 mg + hydrochlorothiazide 6 mg tablet, 30**

| 8477E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.46 | 17.67 | [a] Enalapril/HCT Sandoz [SZ] |
| | | | [B]5.43 | 21.89 | 17.67 | [a] Renitec Plus 20/6 [MK] |

## ▪ FOSINOPRIL + HYDROCHLOROTHIAZIDE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**fosinopril sodium 20 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| 8401E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 19.49 | 20.70 | [a] APO-Fosinopril HCTZ 20/12.5 [TX]<br>[a] Fosinopril/HCT Actavis 20/12.5 [EA] | [a] Fosetic 20/12.5 [ZP] |

## ▪ PERINDOPRIL + INDAPAMIDE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**perindopril arginine 2.5 mg + indapamide hemihydrate 625 microgram tablet, 30**

| 2190G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 13.07 | 14.28 | [a] PREXUM Combi LD 2.5/0.625 [RW] |
| | | | [B]4.19 | 17.26 | 14.28 | [a] Coversyl Plus LD 2.5mg/0.625mg [SE] |

## ▪ PERINDOPRIL + INDAPAMIDE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate) and pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 5 mg perindopril arginine-1.25 mg indapamide hemihydrate) are equivalent for the purposes of substitution.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide-like diuretic.

**perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30**

| 2845R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.83 | 16.04 | [a] Prexum Combi 5/1.25 [RW] |
| | | | [B]4.21 | 19.04 | 16.04 | [a] Coversyl Plus 5mg/1.25mg [SE] |

**perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30**

| 8449Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.83 | 16.04 | [a] Chem mart Perindopril/ Indapamide 4/1.25 [CH]<br>[a] Idaprex Combi 4/1.25 [SZ]<br>[a] Perindopril and Indapamide AN 4/1.25 [EF]<br>[a] Perindopril Combi Actavis 4/1.25 [ED]<br>[a] Terry White Chemists Perindopril/ Indapamide 4/1.25 [TW] | [a] GenRx Perindopril/ Indapamide 4/1.25 [GX]<br>[a] Indosyl Combi 4/1.25 [RW]<br>[a] Perindopril and Indapamide CH 4/1.25 [EA]<br>[a] Perindopril/ Indapamide GH 4/1.25 [GQ] |
| | | | [B]2.51 | 17.34 | 16.04 | [a] Perindo Combi 4/1.25 [AF] | |

## ▪ QUINAPRIL + HYDROCHLOROTHIAZIDE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**quinapril 20 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| 8590D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.85 | 19.06 | Accuretic 20/12.5mg [PF] |

**quinapril 10 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| 8589C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.92 | 18.13 | Accuretic 10/12.5mg [PF] |

*ACE inhibitors and calcium channel blockers*

## ▪ LERCANIDIPINE + ENALAPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**lercanidipine hydrochloride 10 mg + enalapril maleate 20 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9145H NP | 1 | 5 | .. | 16.85 | 18.06 | Zan-Extra 10/20 [GO] |

**lercanidipine hydrochloride 10 mg + enalapril maleate 10 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9144G NP | 1 | 5 | .. | 16.07 | 17.28 | Zan-Extra 10/10 [GO] |

## ▪ PERINDOPRIL + AMLODIPINE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**Restricted benefit**

Stable coronary heart disease

**Clinical criteria:**

- The treatment must not be for the initiation of therapy for coronary heart disease, **AND**
- The condition must be stabilised by treatment with perindopril and amlodipine at the same doses.

**perindopril arginine 5 mg + amlodipine 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9347Y NP | 1 | 5 | .. | 15.53 | 16.74 | [a] APO-Perindopril Arginine/Amlodipine 5/10 [TX] | [a] Reaptan 5/10 [RW] |
| | | | [B]4.40 | 19.93 | 16.74 | [a] Coveram 5/10 [SE] | |

**perindopril arginine 10 mg + amlodipine 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9349C NP | 1 | 5 | .. | 17.05 | 18.26 | [a] APO-Perindopril Arginine/Amlodipine 10/10 [TX] | [a] Reaptan 10/10 [RW] |
| | | | [B]4.34 | 21.39 | 18.26 | [a] Coveram 10/10 [SE] | |

**perindopril arginine 10 mg + amlodipine 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9348B NP | 1 | 5 | .. | 16.36 | 17.57 | [a] APO-Perindopril Arginine/Amlodipine 10/5 [TX] | [a] Reaptan 10/5 [RW] |
| | | | [B]4.28 | 20.64 | 17.57 | [a] Coveram 10/5 [SE] | |

**perindopril arginine 5 mg + amlodipine 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9346X NP | 1 | 5 | .. | 14.84 | 16.05 | [a] APO-Perindopril Arginine/Amlodipine 5/5 [TX] | [a] Reaptan 5/5 [RW] |
| | | | [B]4.31 | 19.15 | 16.05 | [a] Coveram 5/5 [SE] | |

## ▪ RAMIPRIL + FELODIPINE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**ramipril 2.5 mg + felodipine 2.5 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2626F NP | 1 | 5 | .. | 15.39 | 16.60 | Triasyn 2.5/2.5 [SW] |

**ramipril 5 mg + felodipine 5 mg modified release tablet, 30**

| 2629J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.99 | 18.20 | Triasyn 5.0/5.0 [SW] |

## ▪ TRANDOLAPRIL + VERAPAMIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero. The myocardial depressant effects of verapamil hydrochloride and of beta-blocking drugs are additive.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with verapamil.

**trandolapril 4 mg + verapamil hydrochloride 240 mg modified release tablet, 28**

| 2857J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 27.58 | 28.79 | Tarka 4/240 [GO] |

**trandolapril 2 mg + verapamil hydrochloride 180 mg modified release tablet, 28**

| 9387C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 21.51 | 22.72 | Tarka 2/180 [GO] |

## ANGIOTENSIN II ANTAGONISTS, PLAIN

*Angiotensin II antagonists, plain*

## ▪ CANDESARTAN

**candesartan cilexetil 16 mg tablet, 30**

| 8297Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.22 | 16.43 | [a] Adesan [AF] | [a] APO-Candesartan [TX] |
| | | | | | | [a] Auro-Candesartan 16 [DO] | [a] Blooms the Chemist Candesartan [IB] |
| | | | | | | [a] CANDESAN [RF] | [a] Candesartan AN [EA] |
| | | | | | | [a] Candesartan Aspen 16 [RW] | [a] Candesartan GH [GQ] |
| | | | | | | [a] Candesartan Sandoz [SZ] | [a] Chem mart Candesartan [CH] |
| | | | | | | [a] Terry White Chemists Candesartan [TW] | |
| | | | [B]4.00 | 19.22 | 16.43 | [a] Atacand [AP] | |

**candesartan cilexetil 4 mg tablet, 30**

| 8295N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 11.55 | 12.76 | [a] Adesan [AF] | [a] APO-Candesartan [TX] |
| | | | | | | [a] Auro-Candesartan 4 [DO] | [a] Blooms the Chemist Candesartan [IB] |
| | | | | | | [a] CANDESAN [RF] | [a] Candesartan AN [EA] |
| | | | | | | [a] Candesartan Aspen 4 [RW] | [a] Candesartan GH [GQ] |
| | | | | | | [a] Candesartan Sandoz [SZ] | [a] Chem mart Candesartan [CH] |
| | | | | | | [a] Terry White Chemists Candesartan [TW] | |
| | | | [B]4.00 | 15.55 | 12.76 | [a] Atacand [AP] | |

**candesartan cilexetil 32 mg tablet, 30**

| 8889W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.08 | 17.29 | [a] Adesan [AF] | [a] APO-Candesartan [TX] |
| | | | | | | [a] Auro-Candesartan 32 [DO] | [a] Blooms the Chemist Candesartan [IB] |
| | | | | | | [a] CANDESAN [RF] | [a] Candesartan AN [EA] |
| | | | | | | [a] Candesartan Aspen 32 [RW] | [a] Candesartan GH [GQ] |
| | | | | | | [a] Candesartan Sandoz [SZ] | [a] Chem mart Candesartan [CH] |
| | | | | | | [a] Terry White Chemists Candesartan [TW] | |
| | | | [B]6.63 | 22.71 | 17.29 | [a] Atacand [AP] | |

**candesartan cilexetil 8 mg tablet, 30**

| 8296P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 12.48 | 13.69 | [a] Adesan [AF] | [a] APO-Candesartan [TX] |
| | | | | | | [a] Auro-Candesartan 8 [DO] | [a] Blooms the Chemist Candesartan [IB] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] CANDESAN [RF] | [a] Candesartan AN [EA] |
| | | | | | | [a] Candesartan Aspen 8 [RW] | [a] Candesartan Sandoz [SZ] |
| | | | | | | [a] Chem mart Candesartan [CH] | [a] Terry White Chemists Candesartan [TW] |
| | | | [B]4.00 | 16.48 | 13.69 | [a] Atacand [AP] | |

## ▪ EPROSARTAN

### eprosartan 600 mg tablet, 28

| 8447N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | [T]3.50 | 30.08 | 27.79 | Teveten [GO] |

### eprosartan 400 mg tablet, 28

| 8397Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | [T]7.00 | *30.45 | 24.66 | Teveten [GO] |

## ▪ EPROSARTAN

**Authority required**
Adverse effects occurring with all of the base-priced drugs
**Authority required**
Drug interactions occurring with all of the base-priced drugs
**Authority required**
Drug interactions expected to occur with all of the base-priced drugs
**Authority required**
Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance

### eprosartan 600 mg tablet, 28

| 5491B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 30.08 | 31.29 | Teveten [GO] |

### eprosartan 400 mg tablet, 28

| 8951D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *30.45 | 31.66 | Teveten [GO] |

## ▪ IRBESARTAN

### irbesartan 150 mg tablet, 30

| 8247C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 12.93 | 14.14 | [a] Abisart [AF] | [a] APO-Irbesartan [TX] |
| | | | | | | [a] Blooms the Chemist Irbesartan [IB] | [a] Chem mart Irbesartan [CH] |
| | | | | | | [a] Irbesartan Actavis 150 [ED] | [a] Irbesartan AMNEAL [EF] |
| | | | | | | [a] Irbesartan AN [EA] | [a] Irbesartan GH [GQ] |
| | | | | | | [a] Irbesartan RBX [RA] | [a] Irbesartan Sandoz [SZ] |
| | | | | | | [a] Irbesartan Winthrop [WA] | [a] Irprestan 150 [ZP] |
| | | | | | | [a] Terry White Chemists Irbesartan [TW] | |
| | | | [B]1.70 | 14.63 | 14.14 | [a] Avapro [AV] | [a] Karvea [SW] |

### irbesartan 300 mg tablet, 30

| 8248D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.78 | 15.99 | [a] Abisart [AF] | [a] APO-Irbesartan [TX] |
| | | | | | | [a] Blooms the Chemist Irbesartan [IB] | [a] Chem mart Irbesartan [CH] |
| | | | | | | [a] Irbesartan Actavis 300 [ED] | [a] Irbesartan AMNEAL [EF] |
| | | | | | | [a] Irbesartan AN [EA] | [a] Irbesartan GH [GQ] |
| | | | | | | [a] Irbesartan RBX [RA] | [a] Irbesartan Sandoz [SZ] |
| | | | | | | [a] Irbesartan Winthrop [WA] | [a] Irprestan 300 [ZP] |
| | | | | | | [a] Terry White Chemists Irbesartan [TW] | |
| | | | [B]1.71 | 16.49 | 15.99 | [a] Avapro [AV] | [a] Karvea [SW] |

### irbesartan 75 mg tablet, 30

| 8246B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 12.38 | 13.59 | [a] Abisart [AF] | [a] APO-Irbesartan [TX] |
| | | | | | | [a] Blooms the Chemist Irbesartan [IB] | [a] Chem mart Irbesartan [CH] |
| | | | | | | [a] Irbesartan Actavis 75 [ED] | [a] Irbesartan AMNEAL [EF] |
| | | | | | | [a] Irbesartan AN [EA] | [a] Irbesartan GH [GQ] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Irbesartan Sandoz [SZ]<br>[a] Irprestan 75 [ZP] | [a] Irbesartan Winthrop [WA]<br>[a] Terry White Chemists Irbesartan [TW] |
| | | | [B]1.71 | 14.09 | 13.59 | [a] Avapro [AV] | [a] Karvea [SW] |

## ▪ LOSARTAN

### losartan potassium 25 mg tablet, 30

| 5452Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.56 | 17.77 | Cozavan [AF] | |

### losartan potassium 50 mg tablet, 30

| 8203R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *26.73 | 27.94 | Cozavan [AF] | |

## ▪ OLMESARTAN MEDOXOMIL

### olmesartan medoxomil 40 mg tablet, 30

| 2148C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 28.04 | 29.25 | [a] APO-Olmesartan [TX]<br>[a] Olmesartan AN [EA]<br>[a] Olmesartan Sandoz [SZ] | [a] OLMERTAN [RW]<br>[a] Olmesartan - MYL [AF]<br>[a] Pharmacor Olmesartan 40 [CR] |
| | | | [B]3.50 | 31.54 | 29.25 | [a] Olmetec [MK] | |

### olmesartan medoxomil 20 mg tablet, 30

| 2147B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 19.08 | 20.29 | [a] APO-Olmesartan [TX]<br>[a] Olmesartan AN [EA]<br>[a] Olmesartan Sandoz [SZ] | [a] OLMERTAN [RW]<br>[a] Olmesartan - MYL [AF]<br>[a] Pharmacor Olmesartan 20 [CR] |
| | | | [B]3.50 | 22.58 | 20.29 | [a] Olmetec [MK] | |

## ▪ TELMISARTAN

### telmisartan 40 mg tablet, 28

| 8355R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 13.18 | 14.39 | [a] APO-Telmisartan [TX]<br>[a] Mizart [AF]<br>[a] Telmisartan AN [EA]<br>[a] Telmisartan GH [GQ]<br>[a] Teltartan [RW] | [a] Chem mart Telmisartan [CH]<br>[a] Pharmacor Telmisartan 40 [CR]<br>[a] Telmisartan-DRLA [RZ]<br>[a] Telmisartan Sandoz [SZ]<br>[a] Terry White Chemists Telmisartan [TW] |
| | | | [B]2.08 | 15.26 | 14.39 | [a] Micardis [BY] | |

### telmisartan 80 mg tablet, 28

| 8356T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.12 | 18.33 | [a] APO-Telmisartan [TX]<br>[a] Mizart [AF]<br>[a] Telmisartan AN [EA]<br>[a] Telmisartan GH [GQ]<br>[a] Teltartan [RW] | [a] Chem mart Telmisartan [CH]<br>[a] Pharmacor Telmisartan 80 [CR]<br>[a] Telmisartan-DRLA [RZ]<br>[a] Telmisartan Sandoz [SZ]<br>[a] Terry White Chemists Telmisartan [TW] |
| | | | [B]2.09 | 19.21 | 18.33 | [a] Micardis [BY] | |

## ▪ VALSARTAN

### valsartan 80 mg tablet, 28

| 9369D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 19.99 | 21.20 | [a] APO-Valsartan [TX]<br>[a] Diovan [NV] | [a] Dilart [AF] |

### valsartan 160 mg tablet, 28

| 9370E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 22.52 | 23.73 | [a] APO-Valsartan [TX]<br>[a] Diovan [NV] | [a] Dilart [AF] |

**valsartan 40 mg tablet, 28**

| 9368C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 17.20 | 18.41 | [a] APO-Valsartan [TX]<br>[a] Diovan [NV] | [a] Dilart [AF] |

## ▪ VALSARTAN

**Note** No applications for increased maximum quantities and/or repeats will be authorised for the 320 mg tablet.

**valsartan 320 mg tablet, 28**

| 9371F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 25.74 | 26.95 | [a] APO-Valsartan [TX]<br>[a] Diovan [NV] | [a] Dilart [AF] |

## ANGIOTENSIN II ANTAGONISTS, COMBINATIONS

*Angiotensin II antagonists and diuretics*

## ▪ CANDESARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| 9314F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.27 | 17.48 | [a] Adesan HCT 32/12.5 [AF] | [a] APO-Candesartan HCTZ 32/12.5 [TX] |
| | | | | | | [a] Asartan HCT 32/12.5 [DO] | [a] Blooms the Chemist Candesartan HCTZ 32/12.5 [IB] |
| | | | | | | [a] CANDESAN COMBI 32/12.5 [RF] | [a] Candesartan Combi Aspen 32/12.5 [RW] |
| | | | | | | [a] Candesartan HCT GH 32/12.5 [GQ] | [a] Candesartan/HCT Sandoz [SZ] |
| | | | | | | [a] Candesartan HCTZ AN 32/12.5 [EA] | [a] Chem mart Candesartan HCTZ 32/12.5 [CH] |
| | | | | | | [a] Terry White Chemists Candesartan HCTZ 32/12.5 [TW] | |
| | | | [B]9.25 | 25.52 | 17.48 | [a] Atacand Plus 32/12.5 [AP] | |

**candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| 8504N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.52 | 16.73 | [a] Adesan HCT 16/12.5 [AF] | [a] APO-Candesartan HCTZ 16/12.5 [TX] |
| | | | | | | [a] Asartan HCT 16/12.5 [DO] | [a] Blooms the Chemist Candesartan HCTZ 16/12.5 [IB] |
| | | | | | | [a] CANDESAN COMBI 16/12.5 [RF] | [a] Candesartan Combi Aspen 16/12.5 [RW] |
| | | | | | | [a] Candesartan HCT GH 16/12.5 [GQ] | [a] Candesartan/HCT Sandoz [SZ] |
| | | | | | | [a] Candesartan HCTZ AN 16/12.5 [EA] | [a] Chem mart Candesartan HCTZ 16/12.5 [CH] |
| | | | | | | [a] Terry White Chemists Candesartan HCTZ 16/12.5 [TW] | |
| | | | [B]4.00 | 19.52 | 16.73 | [a] Atacand Plus 16/12.5 [AP] | |

**candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30**

| 9315G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.10 | 18.31 | [a] Adesan HCT 32/25 [AF] | [a] APO-Candesartan HCTZ 32/25 [TX] |
| | | | | | | [a] Asartan HCT 32/25 [DO] | [a] Blooms the Chemist Candesartan HCTZ 32/25 [IB] |
| | | | | | | [a] CANDESAN COMBI 32/25 [RF] | [a] Candesartan Combi Aspen 32/25 [RW] |
| | | | | | | [a] Candesartan HCT GH 32/25 [GQ] | [a] Candesartan/HCT Sandoz [SZ] |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | [a] Candesartan HCTZ AN 32/25 [EA] | [a] Chem mart Candesartan HCTZ 32/25 [CH] |
| | | | | | [a] Terry White Chemists Candesartan HCTZ 32/25 [TW] | |
| | | [B]7.75 | 24.85 | 18.31 | [a] Atacand Plus 32/25 [AP] | |

## ▪ EPROSARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

### eprosartan 600 mg + hydrochlorothiazide 12.5 mg tablet, 28

| 8624X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 28.30 | 29.51 | Teveten Plus 600/12.5 [GO] |

## ▪ IRBESARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

### irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30

| 8405J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.96 | 16.17 | [a] Abisart HCT 300/12.5 [AF] | [a] APO-Irbesartan HCTZ [TX] |
| | | | | | | [a] Blooms the Chemist Irbesartan HCTZ 300/12.5 [IB] | [a] Chem mart Irbesartan HCTZ [CH] |
| | | | | | | [a] Irbesartan HCT Actavis 300/12.5 [ED] | [a] Irbesartan HCT GH 300/12.5 [GQ] |
| | | | | | | [a] Irbesartan/HCT Sandoz [SZ] | [a] Irbesartan HCT Winthrop 300/12.5 [WA] |
| | | | | | | [a] Irbesartan HCTZ AMNEAL [EF] | [a] Irbesartan HCTZ AN 300/12.5 [EA] |
| | | | | | | [a] KSART HCT 300/12.5 [RW] | [a] Terry White Chemists Irbesartan HCTZ [TW] |
| | | | [B]1.70 | 16.66 | 16.17 | [a] Avapro HCT 300/12.5 [AV] | [a] Karvezide 300/12.5 [SW] |

### irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30

| 8404H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 13.20 | 14.41 | [a] Abisart HCT 150/12.5 [AF] | [a] APO-Irbesartan HCTZ [TX] |
| | | | | | | [a] Blooms the Chemist Irbesartan HCTZ 150/12.5 [IB] | [a] Chem mart Irbesartan HCTZ [CH] |
| | | | | | | [a] Irbesartan HCT Actavis 150/12.5 [ED] | [a] Irbesartan HCT GH 150/12.5 [GQ] |
| | | | | | | [a] Irbesartan/HCT Sandoz [SZ] | [a] Irbesartan HCT Winthrop 150/12.5 [WA] |
| | | | | | | [a] Irbesartan HCTZ AMNEAL [EF] | [a] Irbesartan HCTZ AN 150/12.5 [EA] |
| | | | | | | [a] Irbesartan/HCTZ RBX 150/12.5 [RA] | [a] KSART HCT 150/12.5 [RW] |
| | | | | | | [a] Terry White Chemists Irbesartan HCTZ [TW] | |
| | | | [B]1.70 | 14.90 | 14.41 | [a] Avapro HCT 150/12.5 [AV] | [a] Karvezide 150/12.5 [SW] |

### irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30

| 2136K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.30 | 16.51 | [a] Abisart HCT 300/25 [AF] | [a] APO-Irbesartan HCTZ [TX] |
| | | | | | | [a] Blooms the Chemist Irbesartan HCTZ 300/25 [IB] | [a] Chem mart Irbesartan HCTZ [CH] |
| | | | | | | [a] Irbesartan HCT Actavis 300/25 [ED] | [a] Irbesartan HCT GH 300/25 [GQ] |
| | | | | | | [a] Irbesartan/HCT Sandoz [SZ] | [a] Irbesartan HCT Winthrop 300/25 [WA] |
| | | | | | | [a] Irbesartan HCTZ AMNEAL [EF] | [a] Irbesartan HCTZ AN 300/25 [EA] |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | [a] Irbesartan/HCTZ RBX 300/25 [RA]<br>[a] Terry White Chemists Irbesartan HCTZ [TW] | [a] KSART HCT 300/25 [RW] |
| | | [B]1.70 | 17.00 | 16.51 | [a] Avapro HCT 300/25 [AV] | [a] Karvezide 300/25 [SW] |

## ▪ OLMESARTAN MEDOXOMIL + HYDROCHLOROTHIAZIDE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

### olmesartan medoxomil 40 mg + hydrochlorothiazide 25 mg tablet, 30

| 2170F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 31.12 | 32.33 | [a] APO-Olmesartan/HCTZ 40/25 [TX]<br>[a] Olmesartan HCT AN 40/25 [EA]<br>[a] Olmesartan/HCT Sandoz [SZ] | [a] OLMERTAN COMBI 40/25 [RW]<br>[a] Olmesartan HCT - MYL 40/25 [AF]<br>[a] Olmetec Plus [MK] |

### olmesartan medoxomil 40 mg + hydrochlorothiazide 12.5 mg tablet, 30

| 2166B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 29.58 | 30.79 | [a] APO-Olmesartan/HCTZ 40/12.5 [TX]<br>[a] Olmesartan HCT AN 40/12.5 [EA]<br>[a] Olmesartan/HCT Sandoz [SZ] | [a] OLMERTAN COMBI 40/12.5 [RW]<br>[a] Olmesartan HCT - MYL 40/12.5 [AF]<br>[a] Olmetec Plus [MK] |

### olmesartan medoxomil 20 mg + hydrochlorothiazide 12.5 mg tablet, 30

| 2161R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 20.63 | 21.84 | [a] APO-Olmesartan/HCTZ 20/12.5 [TX]<br>[a] Olmesartan HCT AN 20/12.5 [EA]<br>[a] Olmesartan/HCT Sandoz [SZ] | [a] OLMERTAN COMBI 20/12.5 [RW]<br>[a] Olmesartan HCT - MYL 20/12.5 [AF]<br>[a] Olmetec Plus [MK] |

## ▪ TELMISARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

### telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28

| 8622T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 13.37 | 14.58 | [a] APO-Telmisartan HCTZ 40/12.5 [TX]<br>[a] Pritor Plus 40/12.5 mg [FI]<br>[a] Telmisartan/HCT Sandoz [SZ]<br>[a] Teltartan HCT 40/12.5 [RW] | [a] Mizart HCT 40/12.5 mg [AF]<br>[a] Telmisartan HCT GH 40/12.5 [GQ]<br>[a] Telmisartan HCTZ AN 40/12.5 [EA] |
| | | | [B]2.69 | 16.06 | 14.58 | [a] Micardis Plus 40/12.5 mg [BY] | |

### telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28

| 8623W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.78 | 17.99 | [a] APO-Telmisartan HCTZ 80/12.5 [TX]<br>[a] Pritor Plus 80/12.5 mg [FI]<br>[a] Telmisartan/HCT Sandoz [SZ]<br>[a] Teltartan HCT 80/12.5 [RW] | [a] Mizart HCT 80/12.5 mg [AF]<br>[a] Telmisartan HCT GH 80/12.5 [GQ]<br>[a] Telmisartan HCTZ AN 80/12.5 [EA] |
| | | | [B]2.69 | 19.47 | 17.99 | [a] Micardis Plus 80/12.5 mg [BY] | |

**telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28**

| 9381R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.28 | 18.49 | [a] APO-Telmisartan HCTZ 80/25 [TX] | [a] Mizart HCT 80/25 mg [AF] |
| | | | | | | [a] Pritor Plus 80/25 mg [FI] | [a] Telmisartan HCT GH 80/25 [GQ] |
| | | | | | | [a] Telmisartan/HCT Sandoz [SZ] | [a] Telmisartan HCTZ AN 80/25 [EA] |
| | | | | | | [a] Teltartan HCT 80/25 [RW] | |
| | | | [B]2.69 | 19.97 | 18.49 | [a] Micardis Plus 80/25 mg [BY] | |

## ▪ VALSARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28**

| 9372G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 21.51 | 22.72 | [a] APO-Valsartan HCTZ 80/12.5 [TX] | [a] Co-Diovan 80/12.5 [NV] |
| | | | | | | [a] Dilart HCT 80/12.5 [AF] | |

**valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28**

| 9373H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 24.04 | 25.25 | [a] APO-Valsartan HCTZ 160/12.5 [TX] | [a] Co-Diovan 160/12.5 [NV] |
| | | | | | | [a] Dilart HCT 160/12.5 [AF] | |

**valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28**

| 9374J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 25.55 | 26.76 | [a] APO-Valsartan HCTZ 160/25 [TX] | [a] Co-Diovan 160/25 [NV] |
| | | | | | | [a] Dilart HCT 160/25 [AF] | |

## ▪ VALSARTAN + HYDROCHLOROTHIAZIDE

**Note** No applications for increased maximum quantities and/or repeats will be authorised for the tablets containing 320 mg valsartan.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28**

| 9482C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 28.78 | 29.99 | [a] APO-Valsartan HCTZ 320/25 [TX] | [a] Co-Diovan 320/25 [NV] |
| | | | | | | [a] Dilart HCT 320/25 [AF] | |

**valsartan 320 mg + hydrochlorothiazide 12.5 mg tablet, 28**

| 9481B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 27.26 | 28.47 | [a] APO-Valsartan HCTZ 320/12.5 [TX] | [a] Co-Diovan 320/12.5 [NV] |
| | | | | | | [a] Dilart HCT 320/12.5 [AF] | |

*Angiotensin II antagonists and calcium channel blockers*

## ▪ AMLODIPINE + VALSARTAN

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**amlodipine 10 mg + valsartan 160 mg tablet, 28**

| 9377M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 23.99 | 25.20 | Exforge 10/160 [NV] |

**amlodipine 5 mg + valsartan 80 mg tablet, 28**

| 9375K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 20.82 | 22.03 | [a] Exforge 5/80 [NV] | [a] Valsartan/Amlodipine Sandoz 80/5 [NM] |

**amlodipine 5 mg + valsartan 320 mg tablet, 28**

| 5459H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 26.57 | 27.78 | Exforge 5/320 [NV] |

**amlodipine 5 mg + valsartan 160 mg tablet, 28**

| 9376L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 23.35 | 24.56 | Exforge 5/160 [NV] |

**amlodipine 10 mg + valsartan 320 mg tablet, 28**

| 5460J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 27.22 | 28.43 | Exforge 10/320 [NV] |

## ▪ OLMESARTAN MEDOXOMIL + AMLODIPINE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30**

| 5294P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 29.62 | 30.83 | [a] Olmesartan/Amlodipine - MYL 40/10 [AF] | [a] Sevikar 40/10 [MK] |

**olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30**

| 5292M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 19.97 | 21.18 | [a] Olmesartan/Amlodipine - MYL 20/5 [AF] | [a] Sevikar 20/5 [MK] |

**olmesartan medoxomil 40 mg + amlodipine 5 mg tablet, 30**

| 5293N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 28.93 | 30.14 | [a] Olmesartan/Amlodipine - MYL 40/5 [AF] | [a] Sevikar 40/5 [MK] |

## ▪ TELMISARTAN + AMLODIPINE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**telmisartan 40 mg + amlodipine 10 mg tablet, 28**

| 8979N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.65 | 15.86 | [a] Pritor/Amlodipine [FI] |
| | | | [B]2.30 | 16.95 | 15.86 | [a] Twynsta [BY] |

**telmisartan 80 mg + amlodipine 5 mg tablet, 28**

| 8980P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.95 | 19.16 | [a] Pritor/Amlodipine [FI] |
| | | | [B]2.14 | 20.09 | 19.16 | [a] Twynsta [BY] |

**telmisartan 40 mg + amlodipine 5 mg tablet, 28**

| 8978M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.00 | 15.21 | [a] Pritor/Amlodipine [FI] |
| | | | [B]2.23 | 16.23 | 15.21 | [a] Twynsta [BY] |

**telmisartan 80 mg + amlodipine 10 mg tablet, 28**

| 8981Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 18.59 | 19.80 | [a] Pritor/Amlodipine [FI] |
| | | | [B]2.19 | 20.78 | 19.80 | [a] Twynsta [BY] |

*Angiotensin II antagonists, other combinations*

## ▪ AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

**amlodipine 10 mg + valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28**

| 5289J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 30.25 | 31.46 | Exforge HCT 10/320/25 [NV] |

**amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28**

| 5286F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 26.38 | 27.59 | Exforge HCT 5/160/25 [NV] |

**amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28**

| 5287G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 25.51 | 26.72 | Exforge HCT 10/160/12.5 [NV] |

**amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28**

| 5285E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 24.86 | 26.07 | [a] Exforge HCT 5/160/12.5 [NV] | [a] Valsartan/Amlodipine/HCT Sandoz 160/5/12.5 [NM] |

**amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28**

| 5288H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 27.02 | 28.23 | Exforge HCT 10/160/25 [NV] |

## ▪ OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

**olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 25 mg tablet, 30**

| 2953K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 33.29 | 34.50 | Sevikar HCT 40/10/25 [MK] |

**olmesartan medoxomil 20 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| 10005N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 21.81 | 23.02 | Sevikar HCT 20/5/12.5 [MK] |

**olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 25 mg tablet, 30**

| 2864R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 32.60 | 33.81 | Sevikar HCT 40/5/25 [MK] |

**olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| 2880N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 30.77 | 31.98 | Sevikar HCT 40/5/12.5 [MK] |

**olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| 2836G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 31.45 | 32.66 | Sevikar HCT 40/10/12.5 [MK] |

## ▪ SACUBITRIL + VALSARTAN

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***6915***

Chronic heart failure

**Clinical criteria:**

- Patient must be symptomatic with NYHA classes II, III or IV, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- Patient must receive concomitant optimal standard chronic heart failure treatment, which must include the maximum tolerated dose of a beta-blocker, unless contraindicated or not tolerated, **AND**
- Patient must have been stabilised on an ACE inhibitor at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- Patient must have been stabilised on an angiotensin II antagonist at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must not be co-administered with an ACE inhibitor or an angiotensin II antagonist.

**sacubitril 97.2 mg + valsartan 102.8 mg tablet, 56**

| 11122J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 202.22 | 38.80 | Entresto [NV] |

**sacubitril 48.6 mg + valsartan 51.4 mg tablet, 56**

| 11131W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 202.22 | 38.80 | Entresto [NV] |

**sacubitril 24.3 mg + valsartan 25.7 mg tablet, 56**

| 11123K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 202.22 | 38.80 | Entresto [NV] |

## LIPID MODIFYING AGENTS

### LIPID MODIFYING AGENTS, PLAIN

*HMG CoA reductase inhibitors*

### ATORVASTATIN

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**atorvastatin 40 mg tablet, 30**

| 8215J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.26 | 15.47 | [a] APO-Atorvastatin [TX] | [a] Atorvachol [ED] |
| | | | | | | [a] Atorvastatin Amneal [EF] | [a] Atorvastatin AN [EA] |
| | | | | | | [a] Atorvastatin GH [GQ] | [a] Atorvastatin Sandoz [SZ] |
| | | | | | | [a] Atorvastatin SCP 40 [RZ] | [a] Atorvastatin SZ [HX] |
| | | | | | | [a] Blooms the Chemist Atorvastatin [IB] | [a] Chem mart Atorvastatin [CH] |
| | | | | | | [a] Lipitor [PF] | [a] Lorstat 40 [AF] |
| | | | | | | [a] Terry White Chemists Atorvastatin [TW] | [a] Torvastat 40 [RW] |
| | | | | | | [a] Trovas [RA] | |

**atorvastatin 10 mg tablet, 30**

| 8213G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 12.62 | 13.83 | [a] APO-Atorvastatin [TX] | [a] Atorvachol [ED] |
| | | | | | | [a] Atorvastatin Amneal [EF] | [a] Atorvastatin AN [EA] |
| | | | | | | [a] Atorvastatin GH [GQ] | [a] Atorvastatin Sandoz [SZ] |
| | | | | | | [a] Atorvastatin SCP 10 [RZ] | [a] Atorvastatin SZ [HX] |
| | | | | | | [a] Blooms the Chemist Atorvastatin [IB] | [a] Chem mart Atorvastatin [CH] |
| | | | | | | [a] Lipitor [PF] | [a] Lorstat 10 [AF] |
| | | | | | | [a] Terry White Chemists Atorvastatin [TW] | [a] Torvastat 10 [RW] |
| | | | | | | [a] Trovas [RA] | |

**atorvastatin 80 mg tablet, 30**

| 8521L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.63 | 16.84 | [a] APO-Atorvastatin [TX] | [a] Atorvachol [ED] |
| | | | | | | [a] Atorvastatin Amneal [EF] | [a] Atorvastatin AN [EA] |
| | | | | | | [a] Atorvastatin GH [GQ] | [a] Atorvastatin Sandoz [SZ] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Atorvastatin SCP 80 [RZ] | [a] Atorvastatin SZ [HX] |
| | | | | | | [a] Blooms the Chemist Atorvastatin [IB] | [a] Chem mart Atorvastatin [CH] |
| | | | | | | [a] Lipitor [PF] | [a] Lorstat 80 [AF] |
| | | | | | | [a] Terry White Chemists Atorvastatin [TW] | [a] Torvastat 80 [RW] |
| | | | | | | [a] Trovas [RA] | |

**atorvastatin 20 mg tablet, 30**

| 8214H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 13.35 | 14.56 | [a] APO-Atorvastatin [TX] | [a] Atorvachol [ED] |
| | | | | | | [a] Atorvastatin Amneal [EF] | [a] Atorvastatin AN [EA] |
| | | | | | | [a] Atorvastatin GH [GQ] | [a] Atorvastatin Sandoz [SZ] |
| | | | | | | [a] Atorvastatin SCP 20 [RZ] | [a] Atorvastatin SZ [HX] |
| | | | | | | [a] Blooms the Chemist Atorvastatin [IB] | [a] Chem mart Atorvastatin [CH] |
| | | | | | | [a] Lipitor [PF] | [a] Lorstat 20 [AF] |
| | | | | | | [a] Terry White Chemists Atorvastatin [TW] | [a] Torvastat 20 [RW] |
| | | | | | | [a] Trovas [RA] | |

## ▪ ATORVASTATIN

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

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**atorvastatin 40 mg tablet, 30**

| 9232X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 11 | .. | 14.26 | 15.47 | [a] APO-Atorvastatin [TX] | [a] Atorvachol [ED] |
| | | | | | | [a] Atorvastatin Amneal [EF] | [a] Atorvastatin AN [EA] |
| | | | | | | [a] Atorvastatin GH [GQ] | [a] Atorvastatin Sandoz [SZ] |
| | | | | | | [a] Atorvastatin SCP 40 [RZ] | [a] Atorvastatin SZ [HX] |
| | | | | | | [a] Blooms the Chemist Atorvastatin [IB] | [a] Chem mart Atorvastatin [CH] |
| | | | | | | [a] Lipitor [PF] | [a] Lorstat 40 [AF] |
| | | | | | | [a] Terry White Chemists Atorvastatin [TW] | [a] Torvastat 40 [RW] |
| | | | | | | [a] Trovas [RA] | |

**atorvastatin 10 mg tablet, 30**

| 9230T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 11 | .. | 12.62 | 13.83 | [a] APO-Atorvastatin [TX] | [a] Atorvachol [ED] |
| | | | | | | [a] Atorvastatin Amneal [EF] | [a] Atorvastatin AN [EA] |
| | | | | | | [a] Atorvastatin GH [GQ] | [a] Atorvastatin Sandoz [SZ] |
| | | | | | | [a] Atorvastatin SCP 10 [RZ] | [a] Atorvastatin SZ [HX] |
| | | | | | | [a] Blooms the Chemist Atorvastatin [IB] | [a] Chem mart Atorvastatin [CH] |
| | | | | | | [a] Lipitor [PF] | [a] Lorstat 10 [AF] |
| | | | | | | [a] Terry White Chemists Atorvastatin [TW] | [a] Torvastat 10 [RW] |
| | | | | | | [a] Trovas [RA] | |

**atorvastatin 80 mg tablet, 30**

| 9233Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 11 | .. | 15.63 | 16.84 | [a] APO-Atorvastatin [TX] | [a] Atorvachol [ED] |
| | | | | | | [a] Atorvastatin Amneal [EF] | [a] Atorvastatin AN [EA] |
| | | | | | | [a] Atorvastatin GH [GQ] | [a] Atorvastatin Sandoz [SZ] |
| | | | | | | [a] Atorvastatin SCP 80 [RZ] | [a] Atorvastatin SZ [HX] |
| | | | | | | [a] Blooms the Chemist Atorvastatin [IB] | [a] Chem mart Atorvastatin [CH] |
| | | | | | | [a] Lipitor [PF] | [a] Lorstat 80 [AF] |
| | | | | | | [a] Terry White Chemists Atorvastatin [TW] | [a] Torvastat 80 [RW] |
| | | | | | | [a] Trovas [RA] | |

**atorvastatin 20 mg tablet, 30**

| 9231W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 11 | .. | 13.35 | 14.56 | [a] APO-Atorvastatin [TX]<br>[a] Atorvastatin Amneal [EF]<br>[a] Atorvastatin GH [GQ]<br>[a] Atorvastatin SCP 20 [RZ]<br>[a] Blooms the Chemist Atorvastatin [IB]<br>[a] Lipitor [PF]<br>[a] Terry White Chemists Atorvastatin [TW]<br>[a] Trovas [RA] | [a] Atorvachol [ED]<br>[a] Atorvastatin AN [EA]<br>[a] Atorvastatin Sandoz [SZ]<br>[a] Atorvastatin SZ [HX]<br>[a] Chem mart Atorvastatin [CH]<br>[a] Lorstat 20 [AF]<br>[a] Torvastat 20 [RW] |

## ▪ FLUVASTATIN

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**fluvastatin 80 mg modified release tablet, 28**

| 2863Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 45.59 | 38.80 | Lescol XL [NV] |

## ▪ FLUVASTATIN

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

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

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**fluvastatin 80 mg modified release tablet, 28**

| 9236D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 11 | .. | 45.59 | 38.80 | Lescol XL [NV] |

## ▪ PRAVASTATIN

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**pravastatin sodium 20 mg tablet, 30**

| 2834E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 13.53 | 14.74 | [a] APO-Pravastatin [TX]<br>[a] Chem mart Pravastatin [CH]<br>[a] Cholvastin [RA]<br>[a] Pravastatin AN [EA]<br>[a] Pravastatin Sandoz [SZ] | [a] Auro-Pravastatin 20 [DO]<br>[a] Cholstat 20 [AF]<br>[a] Lipostat 20 [RF]<br>[a] Pravastatin generichealth [GQ]<br>[a] Terry White Chemists Pravastatin [TW] |
| | | | [B]2.96 | 16.49 | 14.74 | [a] Pravachol [RW] | |

**pravastatin sodium 10 mg tablet, 30**

| 2833D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 12.63 | 13.84 | [a] APO-Pravastatin [TX]<br>[a] Chem mart Pravastatin [CH]<br>[a] Pravastatin AN [EA]<br>[a] Pravastatin Sandoz [SZ] | [a] Auro-Pravastatin 10 [DO]<br>[a] Lipostat 10 [RF]<br>[a] Pravastatin generichealth [GQ]<br>[a] Terry White Chemists Pravastatin [TW] |
| | | | [B]2.94 | 15.57 | 13.84 | [a] Pravachol [RW] | |
| | | | [B]2.95 | 15.58 | 13.84 | [a] Cholstat 10 [AF] | |

**pravastatin sodium 40 mg tablet, 30**

| 8197K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.89 | 16.10 | [a] APO-Pravastatin [TX]<br>[a] Chem mart Pravastatin [CH]<br>[a] Cholvastin [RA]<br>[a] Pravastatin AN [EA]<br>[a] Pravastatin Sandoz [SZ] | [a] Auro-Pravastatin 40 [DO]<br>[a] Cholstat 40 [AF]<br>[a] Lipostat 40 [RF]<br>[a] Pravastatin generichealth [GQ]<br>[a] Terry White Chemists Pravastatin [TW] |
| | | | [B]3.01 | 17.90 | 16.10 | [a] Pravachol [RW] | |

**pravastatin sodium 80 mg tablet, 30**

| 8829Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.93 | 18.14 | [a] APO-Pravastatin [TX]<br>[a] Chem mart Pravastatin [CH]<br>[a] Pravastatin AN [EA]<br>[a] Pravastatin Sandoz [SZ] | [a] Auro-Pravastatin 80 [DO]<br>[a] Lipostat 80 [RF]<br>[a] Pravastatin generichealth [GQ]<br>[a] Terry White Chemists Pravastatin [TW] |
| | | | [B]3.01 | 19.94 | 18.14 | [a] Pravachol [RW] | |

## ▪ PRAVASTATIN

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

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**pravastatin sodium 20 mg tablet, 30**

| 9238F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 11 | .. | 13.53 | 14.74 | [a] APO-Pravastatin [TX]<br>[a] Chem mart Pravastatin [CH]<br>[a] Cholvastin [RA]<br>[a] Pravastatin AN [EA]<br>[a] Pravastatin Sandoz [SZ] | [a] Auro-Pravastatin 20 [DO]<br>[a] Cholstat 20 [AF]<br>[a] Lipostat 20 [RF]<br>[a] Pravastatin generichealth [GQ]<br>[a] Terry White Chemists Pravastatin [TW] |
| | | | [B]2.96 | 16.49 | 14.74 | [a] Pravachol [RW] | |

**pravastatin sodium 10 mg tablet, 30**

| 9237E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 11 | .. | 12.63 | 13.84 | [a] APO-Pravastatin [TX]<br>[a] Chem mart Pravastatin [CH]<br>[a] Pravastatin AN [EA]<br>[a] Pravastatin Sandoz [SZ] | [a] Auro-Pravastatin 10 [DO]<br>[a] Lipostat 10 [RF]<br>[a] Pravastatin generichealth [GQ]<br>[a] Terry White Chemists Pravastatin [TW] |
| | | | [B]2.94 | 15.57 | 13.84 | [a] Pravachol [RW] | |
| | | | [B]2.95 | 15.58 | 13.84 | [a] Cholstat 10 [AF] | |

**pravastatin sodium 40 mg tablet, 30**

| 9239G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 11 | .. | 14.89 | 16.10 | [a] APO-Pravastatin [TX]<br>[a] Chem mart Pravastatin [CH]<br>[a] Cholvastin [RA]<br>[a] Pravastatin AN [EA]<br>[a] Pravastatin Sandoz [SZ] | [a] Auro-Pravastatin 40 [DO]<br>[a] Cholstat 40 [AF]<br>[a] Lipostat 40 [RF]<br>[a] Pravastatin generichealth [GQ]<br>[a] Terry White Chemists Pravastatin [TW] |
| | | | [B]3.01 | 17.90 | 16.10 | [a] Pravachol [RW] | |

**pravastatin sodium 80 mg tablet, 30**

| 9240H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 11 | .. | 16.93 | 18.14 | [a] APO-Pravastatin [TX]<br>[a] Chem mart Pravastatin [CH]<br>[a] Pravastatin AN [EA]<br>[a] Pravastatin Sandoz [SZ] | [a] Auro-Pravastatin 80 [DO]<br>[a] Lipostat 80 [RF]<br>[a] Pravastatin generichealth [GQ]<br>[a] Terry White Chemists Pravastatin [TW] |
| | | | [B]3.01 | 19.94 | 18.14 | [a] Pravachol [RW] | |

## ▪ ROSUVASTATIN

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**rosuvastatin 20 mg tablet, 30**

| 2574L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 18.95 | 20.16 | [a] APO-Rosuvastatin [TX]<br>[a] Cavstat [AF]<br>[a] Crestor [AP]<br>[a] Rosuvastatin Actavis 20 [ED] | [a] Blooms the Chemist Rosuvastatin [IB]<br>[a] Chem mart Rosuvastatin [CH]<br>[a] Crosuva 20 [ZP]<br>[a] Rosuvastatin AMNEAL [EF] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Rosuvastatin-DRLA [RI] | [a] Rosuvastatin generichealth [HQ] |
| | | | | | | [a] Rosuvastatin GH [GQ] | [a] Terry White Chemists Rosuvastatin [TW] |

**rosuvastatin 10 mg tablet, 30**

| 2628H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.62 | 17.83 | [a] APO-Rosuvastatin [TX] | [a] Blooms the Chemist Rosuvastatin [IB] |
| | | | | | | [a] Cavstat [AF] | [a] Chem mart Rosuvastatin [CH] |
| | | | | | | [a] Crestor [AP] | [a] Crosuva 10 [ZP] |
| | | | | | | [a] Rosuvastatin Actavis 10 [ED] | [a] Rosuvastatin AMNEAL [EF] |
| | | | | | | [a] Rosuvastatin-DRLA [RI] | [a] Rosuvastatin generichealth [HQ] |
| | | | | | | [a] Rosuvastatin GH [GQ] | [a] Terry White Chemists Rosuvastatin [TW] |

**rosuvastatin 5 mg tablet, 30**

| 2606E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.85 | 16.06 | [a] APO-Rosuvastatin [TX] | [a] Blooms the Chemist Rosuvastatin [IB] |
| | | | | | | [a] Cavstat [AF] | [a] Chem mart Rosuvastatin [CH] |
| | | | | | | [a] Crestor [AP] | [a] Crosuva 5 [ZP] |
| | | | | | | [a] Rosuvastatin AMNEAL [EF] | [a] Rosuvastatin-DRLA [RI] |
| | | | | | | [a] Rosuvastatin generichealth [HQ] | [a] Rosuvastatin GH [GQ] |
| | | | | | | [a] Terry White Chemists Rosuvastatin [TW] | |

**rosuvastatin 40 mg tablet, 30**

| 2594M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 22.30 | 23.51 | [a] APO-Rosuvastatin [TX] | [a] Blooms the Chemist Rosuvastatin [IB] |
| | | | | | | [a] Cavstat [AF] | [a] Chem mart Rosuvastatin [CH] |
| | | | | | | [a] Crestor [AP] | [a] Crosuva 40 [ZP] |
| | | | | | | [a] Rosuvastatin Actavis 40 [ED] | [a] Rosuvastatin AMNEAL [EF] |
| | | | | | | [a] Rosuvastatin-DRLA [RI] | [a] Rosuvastatin generichealth [HQ] |
| | | | | | | [a] Rosuvastatin GH [GQ] | [a] Terry White Chemists Rosuvastatin [TW] |

## ▪ ROSUVASTATIN

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Clinical criteria:**

- The treatment must not be prescribed for hypercholesterolaemia if the patient has heterozygous familial hypercholesterolaemia.

**rosuvastatin 20 mg tablet, 30**

| 9044B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 18.95 | 20.16 | [a] APO-Rosuvastatin [TX] | [a] Blooms the Chemist Rosuvastatin [IB] |
| | | | | | | [a] Cavstat [AF] | [a] Chem mart Rosuvastatin [CH] |
| | | | | | | [a] Crestor [AP] | [a] Crosuva 20 [ZP] |
| | | | | | | [a] Rostor 20 [DO] | [a] Rosuvastatin Actavis 20 [ED] |
| | | | | | | [a] Rosuvastatin AMNEAL [EF] | [a] Rosuvastatin-DRLA [RI] |
| | | | | | | [a] Rosuvastatin generichealth [HQ] | [a] Rosuvastatin GH [GQ] |
| | | | | | | [a] Rosuvastatin RBX [RA] | [a] Rosuvastatin Sandoz [SZ] |
| | | | | | | [a] Terry White Chemists Rosuvastatin [TW] | |

**rosuvastatin 10 mg tablet, 30**

| 9043Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.62 | 17.83 | [a] APO-Rosuvastatin [TX] | [a] Blooms the Chemist Rosuvastatin [IB] |
| | | | | | | [a] Cavstat [AF] | [a] Chem mart Rosuvastatin [CH] |
| | | | | | | [a] Crestor [AP] | [a] Crosuva 10 [ZP] |
| | | | | | | [a] Rostor 10 [DO] | [a] Rosuvastatin Actavis 10 [ED] |
| | | | | | | [a] Rosuvastatin AMNEAL [EF] | [a] Rosuvastatin-DRLA [RI] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Rosuvastatin generichealth [HQ] | [a] Rosuvastatin GH [GQ] |
| | | | | | | [a] Rosuvastatin RBX [RA] | [a] Rosuvastatin Sandoz [SZ] |
| | | | | | | [a] Terry White Chemists Rosuvastatin [TW] | |

**rosuvastatin 5 mg tablet, 30**

| 9042X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.85 | 16.06 | [a] APO-Rosuvastatin [TX] | [a] Blooms the Chemist Rosuvastatin [IB] |
| | | | | | | [a] Cavstat [AF] | [a] Chem mart Rosuvastatin [CH] |
| | | | | | | [a] Crestor [AP] | [a] Crosuva 5 [ZP] |
| | | | | | | [a] Rostor 5 [DO] | [a] Rosuvastatin AMNEAL [EF] |
| | | | | | | [a] Rosuvastatin-DRLA [RI] | [a] Rosuvastatin generichealth [HQ] |
| | | | | | | [a] Rosuvastatin GH [GQ] | [a] Rosuvastatin RBX [RA] |
| | | | | | | [a] Rosuvastatin Sandoz [SZ] | [a] Terry White Chemists Rosuvastatin [TW] |

**rosuvastatin 40 mg tablet, 30**

| 9045C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 22.30 | 23.51 | [a] APO-Rosuvastatin [TX] | [a] Blooms the Chemist Rosuvastatin [IB] |
| | | | | | | [a] Cavstat [AF] | [a] Chem mart Rosuvastatin [CH] |
| | | | | | | [a] Crestor [AP] | [a] Crosuva 40 [ZP] |
| | | | | | | [a] Rostor 40 [DO] | [a] Rosuvastatin Actavis 40 [ED] |
| | | | | | | [a] Rosuvastatin AMNEAL [EF] | [a] Rosuvastatin-DRLA [RI] |
| | | | | | | [a] Rosuvastatin generichealth [HQ] | [a] Rosuvastatin GH [GQ] |
| | | | | | | [a] Rosuvastatin RBX [RA] | [a] Rosuvastatin Sandoz [SZ] |
| | | | | | | [a] Terry White Chemists Rosuvastatin [TW] | |

## ▪ ROSUVASTATIN

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

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

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**rosuvastatin 20 mg tablet, 30**

| 2609H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 11 | .. | 18.95 | 20.16 | [a] APO-Rosuvastatin [TX] | [a] Blooms the Chemist Rosuvastatin [IB] |
| | | | | | | [a] Cavstat [AF] | [a] Chem mart Rosuvastatin [CH] |
| | | | | | | [a] Crestor [AP] | [a] Crosuva 20 [ZP] |
| | | | | | | [a] Rosuvastatin Actavis 20 [ED] | [a] Rosuvastatin AMNEAL [EF] |
| | | | | | | [a] Rosuvastatin-DRLA [RI] | [a] Rosuvastatin generichealth [HQ] |
| | | | | | | [a] Rosuvastatin GH [GQ] | [a] Terry White Chemists Rosuvastatin [TW] |

**rosuvastatin 10 mg tablet, 30**

| 2584B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 11 | .. | 16.62 | 17.83 | [a] APO-Rosuvastatin [TX] | [a] Blooms the Chemist Rosuvastatin [IB] |
| | | | | | | [a] Cavstat [AF] | [a] Chem mart Rosuvastatin [CH] |
| | | | | | | [a] Crestor [AP] | [a] Crosuva 10 [ZP] |
| | | | | | | [a] Rosuvastatin Actavis 10 [ED] | [a] Rosuvastatin AMNEAL [EF] |
| | | | | | | [a] Rosuvastatin-DRLA [RI] | [a] Rosuvastatin generichealth [HQ] |
| | | | | | | [a] Rosuvastatin GH [GQ] | [a] Terry White Chemists Rosuvastatin [TW] |

**rosuvastatin 5 mg tablet, 30**

| 2590H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 11 | .. | 14.85 | 16.06 | [a] APO-Rosuvastatin [TX] | [a] Blooms the Chemist Rosuvastatin [IB] |
| | | | | | | [a] Cavstat [AF] | [a] Chem mart Rosuvastatin [CH] |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | [a] Crestor [AP]<br>[a] Rosuvastatin AMNEAL [EF]<br>[a] Rosuvastatin generichealth [HQ]<br>[a] Terry White Chemists Rosuvastatin [TW] | [a] Crosuva 5 [ZP]<br>[a] Rosuvastatin-DRLA [RI]<br>[a] Rosuvastatin GH [GQ] |

**rosuvastatin 40 mg tablet, 30**

| 2636R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 11 | .. | 22.30 | 23.51 | [a] APO-Rosuvastatin [TX]<br>[a] Cavstat [AF]<br>[a] Crestor [AP]<br>[a] Rosuvastatin Actavis 40 [ED]<br>[a] Rosuvastatin-DRLA [RI]<br>[a] Rosuvastatin GH [GQ] | [a] Blooms the Chemist Rosuvastatin [IB]<br>[a] Chem mart Rosuvastatin [CH]<br>[a] Crosuva 40 [ZP]<br>[a] Rosuvastatin AMNEAL [EF]<br>[a] Rosuvastatin generichealth [HQ]<br>[a] Terry White Chemists Rosuvastatin [TW] |

## ▪ ROSUVASTATIN

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

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements, **AND**
- The treatment must not be prescribed for hypercholesterolaemia if the patient has heterozygous familial hypercholesterolaemia.

**rosuvastatin 20 mg tablet, 30**

| 3404E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 11 | .. | 18.95 | 20.16 | [a] APO-Rosuvastatin [TX]<br>[a] Cavstat [AF]<br>[a] Crestor [AP]<br>[a] Rostor 20 [DO]<br>[a] Rosuvastatin AMNEAL [EF]<br>[a] Rosuvastatin generichealth [HQ]<br>[a] Rosuvastatin RBX [RA]<br>[a] Terry White Chemists Rosuvastatin [TW] | [a] Blooms the Chemist Rosuvastatin [IB]<br>[a] Chem mart Rosuvastatin [CH]<br>[a] Crosuva 20 [ZP]<br>[a] Rosuvastatin Actavis 20 [ED]<br>[a] Rosuvastatin-DRLA [RI]<br>[a] Rosuvastatin GH [GQ]<br>[a] Rosuvastatin Sandoz [SZ] |

**rosuvastatin 10 mg tablet, 30**

| 3403D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 11 | .. | 16.62 | 17.83 | [a] APO-Rosuvastatin [TX]<br>[a] Cavstat [AF]<br>[a] Crestor [AP]<br>[a] Rostor 10 [DO]<br>[a] Rosuvastatin AMNEAL [EF]<br>[a] Rosuvastatin generichealth [HQ]<br>[a] Rosuvastatin RBX [RA]<br>[a] Terry White Chemists Rosuvastatin [TW] | [a] Blooms the Chemist Rosuvastatin [IB]<br>[a] Chem mart Rosuvastatin [CH]<br>[a] Crosuva 10 [ZP]<br>[a] Rosuvastatin Actavis 10 [ED]<br>[a] Rosuvastatin-DRLA [RI]<br>[a] Rosuvastatin GH [GQ]<br>[a] Rosuvastatin Sandoz [SZ] |

**rosuvastatin 5 mg tablet, 30**

| 3402C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 11 | .. | 14.85 | 16.06 | [a] APO-Rosuvastatin [TX]<br>[a] Cavstat [AF]<br>[a] Crestor [AP]<br>[a] Rostor 5 [DO]<br>[a] Rosuvastatin-DRLA [RI]<br>[a] Rosuvastatin GH [GQ]<br>[a] Rosuvastatin Sandoz [SZ] | [a] Blooms the Chemist Rosuvastatin [IB]<br>[a] Chem mart Rosuvastatin [CH]<br>[a] Crosuva 5 [ZP]<br>[a] Rosuvastatin AMNEAL [EF]<br>[a] Rosuvastatin generichealth [HQ]<br>[a] Rosuvastatin RBX [RA]<br>[a] Terry White Chemists Rosuvastatin [TW] |

**rosuvastatin 40 mg tablet, 30**

| 3405F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 11 | .. | 22.30 | 23.51 | [a] APO-Rosuvastatin [TX] | [a] Blooms the Chemist Rosuvastatin [IB] |
| | | | | | | [a] Cavstat [AF] | [a] Chem mart Rosuvastatin [CH] |
| | | | | | | [a] Crestor [AP] | [a] Crosuva 40 [ZP] |
| | | | | | | [a] Rostor 40 [DO] | [a] Rosuvastatin Actavis 40 [ED] |
| | | | | | | [a] Rosuvastatin AMNEAL [EF] | [a] Rosuvastatin-DRLA [RI] |
| | | | | | | [a] Rosuvastatin generichealth [HQ] | [a] Rosuvastatin GH [GQ] |
| | | | | | | [a] Rosuvastatin RBX [RA] | [a] Rosuvastatin Sandoz [SZ] |
| | | | | | | [a] Terry White Chemists Rosuvastatin [TW] | |

## ▪ SIMVASTATIN

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**simvastatin 80 mg tablet, 30**

| 8313M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.42 | 15.63 | [a] APO-Simvastatin [TX] | [a] Auro-Simvastatin 80 [DO] |
| | | | | | | [a] Chem mart Simvastatin [CH] | [a] Ransim [RA] |
| | | | | | | [a] Simvacor 80 [CR] | [a] Simvar 80 [RW] |
| | | | | | | [a] Simvastatin AN [EA] | [a] Simvastatin-GA 80 [ED] |
| | | | | | | [a] Simvastatin generichealth [GQ] | [a] Simvastatin Sandoz [SZ] |
| | | | | | | [a] Terry White Chemists Simvastatin [TW] | [a] Zimstat [AF] |
| | | | [B]8.46 | 22.88 | 15.63 | [a] Lipex 80 [FR] | [a] Zocor [MK] |

**simvastatin 10 mg tablet, 30**

| 2011W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 12.21 | 13.42 | [a] APO-Simvastatin [TX] | [a] Auro-Simvastatin 10 [DO] |
| | | | | | | [a] Chem mart Simvastatin [CH] | [a] Ransim [RA] |
| | | | | | | [a] Simvacor 10 [CR] | [a] Simvar 10 [RW] |
| | | | | | | [a] Simvastatin AN [EA] | [a] Simvastatin-GA 10 [ED] |
| | | | | | | [a] Simvastatin generichealth [GQ] | [a] Simvastatin Sandoz [SZ] |
| | | | | | | [a] Terry White Chemists Simvastatin [TW] | [a] Zimstat [AF] |
| | | | [B]5.33 | 17.54 | 13.42 | [a] Lipex 10 [FR] | [a] Zocor [MK] |

**simvastatin 5 mg tablet, 30**

| 2013Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 11.91 | 13.12 | [a] Simvastatin Sandoz [SZ] | [a] Zimstat [AF] |

**simvastatin 40 mg tablet, 30**

| 8173E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 13.42 | 14.63 | [a] APO-Simvastatin [TX] | [a] Auro-Simvastatin 40 [DO] |
| | | | | | | [a] Chem mart Simvastatin [CH] | [a] Ransim [RA] |
| | | | | | | [a] Simvacor 40 [CR] | [a] Simvar 40 [RW] |
| | | | | | | [a] Simvastatin AN [EA] | [a] Simvastatin-GA 40 [ED] |
| | | | | | | [a] Simvastatin generichealth [GQ] | [a] Simvastatin Sandoz [SZ] |
| | | | | | | [a] Terry White Chemists Simvastatin [TW] | [a] Zimstat [AF] |
| | | | [B]5.36 | 18.78 | 14.63 | [a] Lipex 40 [FR] | [a] Zocor [MK] |

**simvastatin 20 mg tablet, 30**

| 2012X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 12.71 | 13.92 | [a] APO-Simvastatin [TX] | [a] Auro-Simvastatin 20 [DO] |
| | | | | | | [a] Chem mart Simvastatin [CH] | [a] Ransim [RA] |
| | | | | | | [a] Simvacor 20 [CR] | [a] Simvar 20 [RW] |
| | | | | | | [a] Simvastatin AN [EA] | [a] Simvastatin-GA 20 [ED] |
| | | | | | | [a] Simvastatin generichealth [GQ] | [a] Simvastatin Sandoz [SZ] |
| | | | | | | [a] Terry White Chemists Simvastatin [TW] | [a] Zimstat [AF] |
| | | | [B]5.37 | 18.08 | 13.92 | [a] Lipex 20 [FR] | [a] Zocor [MK] |

## ▪ SIMVASTATIN

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

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

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**simvastatin 80 mg tablet, 30**

| 9245N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 11 | .. | 14.42 | 15.63 | [a] APO-Simvastatin [TX]<br>[a] Chem mart Simvastatin [CH]<br>[a] Simvacor 80 [CR]<br>[a] Simvastatin AN [EA]<br>[a] Simvastatin generichealth [GQ]<br>[a] Terry White Chemists Simvastatin [TW] | [a] Auro-Simvastatin 80 [DO]<br>[a] Ransim [RA]<br>[a] Simvar 80 [RW]<br>[a] Simvastatin-GA 80 [ED]<br>[a] Simvastatin Sandoz [SZ]<br>[a] Zimstat [AF] |
| | | | [B] 8.46 | 22.88 | 15.63 | [a] Lipex 80 [FR] | [a] Zocor [MK] |

**simvastatin 10 mg tablet, 30**

| 9242K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 11 | .. | 12.21 | 13.42 | [a] APO-Simvastatin [TX]<br>[a] Chem mart Simvastatin [CH]<br>[a] Simvacor 10 [CR]<br>[a] Simvastatin AN [EA]<br>[a] Simvastatin generichealth [GQ]<br>[a] Terry White Chemists Simvastatin [TW] | [a] Auro-Simvastatin 10 [DO]<br>[a] Ransim [RA]<br>[a] Simvar 10 [RW]<br>[a] Simvastatin-GA 10 [ED]<br>[a] Simvastatin Sandoz [SZ]<br>[a] Zimstat [AF] |
| | | | [B] 5.33 | 17.54 | 13.42 | [a] Lipex 10 [FR] | [a] Zocor [MK] |

**simvastatin 5 mg tablet, 30**

| 9241J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 11 | .. | 11.91 | 13.12 | [a] Simvastatin Sandoz [SZ] | [a] Zimstat [AF] |

**simvastatin 40 mg tablet, 30**

| 9244M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 11 | .. | 13.42 | 14.63 | [a] APO-Simvastatin [TX]<br>[a] Chem mart Simvastatin [CH]<br>[a] Simvacor 40 [CR]<br>[a] Simvastatin AN [EA]<br>[a] Simvastatin generichealth [GQ]<br>[a] Terry White Chemists Simvastatin [TW] | [a] Auro-Simvastatin 40 [DO]<br>[a] Ransim [RA]<br>[a] Simvar 40 [RW]<br>[a] Simvastatin-GA 40 [ED]<br>[a] Simvastatin Sandoz [SZ]<br>[a] Zimstat [AF] |
| | | | [B] 5.36 | 18.78 | 14.63 | [a] Lipex 40 [FR] | [a] Zocor [MK] |

**simvastatin 20 mg tablet, 30**

| 9243L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 11 | .. | 12.71 | 13.92 | [a] APO-Simvastatin [TX]<br>[a] Chem mart Simvastatin [CH]<br>[a] Simvacor 20 [CR]<br>[a] Simvastatin AN [EA]<br>[a] Simvastatin generichealth [GQ]<br>[a] Terry White Chemists Simvastatin [TW] | [a] Auro-Simvastatin 20 [DO]<br>[a] Ransim [RA]<br>[a] Simvar 20 [RW]<br>[a] Simvastatin-GA 20 [ED]<br>[a] Simvastatin Sandoz [SZ]<br>[a] Zimstat [AF] |
| | | | [B] 5.37 | 18.08 | 13.92 | [a] Lipex 20 [FR] | [a] Zocor [MK] |

*Fibrates*

## ▪ FENOFIBRATE

**Note** The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**fenofibrate 48 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9022W NP | 1 | 5 | .. | 30.60 | 31.81 | Lipidil [GO] |

**fenofibrate 145 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9023X NP | 1 | 5 | .. | 40.38 | 38.80 | Lipidil [GO] |

## ▪ FENOFIBRATE

**Note** The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

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

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

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**fenofibrate 48 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9246P | 1 | 11 | .. | 30.60 | 31.81 | Lipidil [GO] |

**fenofibrate 145 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9247Q | 1 | 11 | .. | 40.38 | 38.80 | Lipidil [GO] |

## ▪ GEMFIBROZIL

**Note** The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**gemfibrozil 600 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1453L NP | 1 | 5 | .. | 20.99 | 22.20 | [a] Ausgem [RW] | [a] Lipigem [AF] |

## ▪ GEMFIBROZIL

**Note** The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

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

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

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**gemfibrozil 600 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9248R | 1 | 11 | .. | 20.99 | 22.20 | [a] Ausgem [RW] | [a] Lipigem [AF] |

*Bile acid sequestrants*

## ▪ CHOLESTYRAMINE

**cholestyramine 4 g powder for oral liquid, 50 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2967E NP | 2 | 5 | .. | *80.51 | 38.80 | Questran Lite [QA] |

## ▪ CHOLESTYRAMINE

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

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

**Restricted benefit**

Primary hypercholesterolaemia

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**cholestyramine 4 g powder for oral liquid, 50 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9249T | 2 | 11 | .. | *80.51 | 38.80 | Questran Lite [QA] |

*Other lipid modifying agents*

## ▪ EVOLOCUMAB

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Familial homozygous hypercholesterolaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 7, **AND**
- Patient must have an LDL cholesterol level in excess of 3.3 millimoles per litre after at least 3 months of treatment at a maximum tolerated dose of an HMG CoA reductase inhibitor (statin), in conjunction with dietary therapy and exercise; OR
- Patient must have an LDL cholesterol level in excess of 3.3 millimoles per litre after having developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a withdrawal of statin treatment; OR
- Patient must have an LDL cholesterol level in excess of 3.3 millimoles per litre and must be one in whom treatment with an HMG CoA reductase inhibitor (statin) is contraindicated.

**Treatment criteria:**

- Must be treated by a consultant physician or in consultation with a consultant physician.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

The date of the consultation with a consultant physician must be no more than 6 months prior to the application for a PBS authority. The full name of the consultant physician consulted and the date of consultation are to be provided at the time of application.

The qualifying LDL cholesterol level must be provided at the time of application and must be no more than 2 months old. With the exception of patients contraindicated to a statin, the agent, dose and duration of statin treatment must be provided at the time of application.

The authority application must be made in writing and must include:

a) A completed authority prescription form; and

b) A completed Familial homozygous hypercholesterolaemia Initial PBS Authority Application - Supporting Information Form; and

c) The date of consultation and the full name of the consultant physician; and

d) A copy of the qualifying Dutch Lipid Clinic Network Score or a copy of the result of genetic testing; and

e) The result of LDL cholesterol level and one of the following where appropriate: statin treatment details including agent, dose and treatment duration; or details of adverse event or contraindication to treatment with a statin as defined in the TGA-approved Product Information.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Familial homozygous hypercholesterolaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in conjunction with dietary therapy and exercise.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Familial homozygous hypercholesterolaemia

Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2016, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 7, **AND**
- Patient must have had an LDL cholesterol level in excess of 3.3 millimoles per litre after at least 3 months of treatment at a maximum tolerated dose of an HMG CoA reductase inhibitor (statin), in conjunction with dietary therapy and exercise, prior to initiation of treatment with this drug; OR
- Patient must have had an LDL cholesterol level in excess of 3.3 millimoles per litre after having developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a withdrawal of statin treatment, prior to initiation of treatment with this drug; OR
- Patient must have had an LDL cholesterol level in excess of 3.3 millimoles per litre prior to initiation of treatment with this drug, and must be contraindicated to treatment with an HMG CoA reductase inhibitor (statin).

**Treatment criteria:**

- Must be treated by a consultant physician or in consultation with a consultant physician.

The date of the consultation with a consultant physician must be no more than 6 months prior to the application for a PBS authority. The full name of the consultant physician consulted and the date of consultation are to be provided at the time of application.

The qualifying LDL cholesterol level prior to initiation of treatment with this drug must be provided at the time of application. With the exception of patients contraindicated to a statin, the agent, dose and duration of statin treatment must be provided at the time of application.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

The authority application must be made in writing and must include:

a) A completed authority prescription form; and

b) A completed Familial homozygous hypercholesterolaemia Initial PBS 'Grandfather' Authority Application - Supporting Information Form; and

c) The date of consultation and the full name of the consultant physician; and

d) A copy of the qualifying Dutch Lipid Clinic Network Score or a copy of the result of genetic testing; and

e) The result of LDL cholesterol level and one of the following where appropriate: statin treatment details including agent, dose and treatment duration; or details of adverse event or contraindication to treatment with a statin as defined in the TGA-approved Product Information.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### evolocumab 140 mg/mL injection, 1 mL injection device

10958R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *943.15 | 38.80 | Repatha [AN] |

## ▪ EZETIMIBE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***5537***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***5543***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***5538***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***5544***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***5594***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***5586***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***5575***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be

documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***5576***

Hypercholesterolaemia

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
- Patient must be one in whom treatment with an HMG CoA reductase inhibitor (statin) is contraindicated.

**Authority required (STREAMLINED)**

***5562***

Hypercholesterolaemia

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose; OR
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a withdrawal of the statin treatment.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

**Authority required (STREAMLINED)**

***5563***

Homozygous sitosterolaemia

**Authority required (STREAMLINED)**

***5577***

Hypercholesterolaemia

**Clinical criteria:**

- Patient must have homozygous familial hypercholesterolaemia, **AND**
- Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin).

**ezetimibe 10 mg tablet, 30**

8757X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 66.84 | 38.80 | Ezetrol [MK] |

NP

## LIPID MODIFYING AGENTS, COMBINATIONS

*HMG CoA reductase inhibitors in combination with other lipid modifying agents*

### ▪ EZETIMIBE + ATORVASTATIN

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***4068***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4085***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4086***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4069***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4096***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4120***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4121***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4097***

Hypercholesterolaemia

**Clinical criteria:**

- Patient must have homozygous familial hypercholesterolaemia, **AND**
- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

### ezetimibe 10 mg + atorvastatin 20 mg tablet, 30

10393B

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 69.10 | 38.80 | Atozet [MK] |

**ezetimibe 10 mg + atorvastatin 80 mg tablet, 30**

| 10376D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 71.38 | 38.80 | Atozet [MK] |

**ezetimibe 10 mg + atorvastatin 40 mg tablet, 30**

| 10377E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 70.01 | 38.80 | Atozet [MK] |

## ▪ EZETIMIBE + ATORVASTATIN

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***4068***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4085***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4086***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4069***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4096***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4120***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4121***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4097***

Hypercholesterolaemia

**Clinical criteria:**

- Patient must have homozygous familial hypercholesterolaemia, **AND**
- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

**Authority required (STREAMLINED)**

***4353***

Hypercholesterolaemia

**Clinical criteria:**

- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs), **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the atorvastatin dose.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

**ezetimibe 10 mg + atorvastatin 10 mg tablet, 30**

| 10392Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 68.37 | 38.80 | Atozet [MK] |

## ▪ EZETIMIBE + SIMVASTATIN

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***4068***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be

documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4085***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4086***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4069***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4096***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4120***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4121***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4097***

Hypercholesterolaemia

**Clinical criteria:**

- Patient must have homozygous familial hypercholesterolaemia, **AND**
- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

**ezetimibe 10 mg + simvastatin 80 mg tablet, 30**

8882L

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 70.17 | 38.80 | Vytorin [MK] |

**ezetimibe 10 mg + simvastatin 40 mg tablet, 30**

8881K

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 69.17 | 38.80 | Vytorin [MK] |

## ▪ EZETIMIBE + SIMVASTATIN

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***4068***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4085***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4086***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4069***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4096***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4120***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4121***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be

documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4097***

Hypercholesterolaemia

**Clinical criteria:**

- Patient must have homozygous familial hypercholesterolaemia, **AND**
- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

**Authority required (STREAMLINED)**

***4147***

Hypercholesterolaemia

**Clinical criteria:**

- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs), **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

**ezetimibe 10 mg + simvastatin 20 mg tablet, 30**

| 9484E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 68.46 | 38.80 | Vytorin [MK] |

**ezetimibe 10 mg + simvastatin 10 mg tablet, 30**

| 9483D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 67.96 | 38.80 | Vytorin [MK] |

## ▪ ROSUVASTATIN (&) EZETIMIBE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***4068***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4085***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4086***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4069***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4096***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be

documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4120***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4121***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4097***

Hypercholesterolaemia

**Clinical criteria:**

- Patient must have homozygous familial hypercholesterolaemia, **AND**
- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

**rosuvastatin 40 mg tablet [30] (&) ezetimibe 10 mg tablet [30 tablets], 1 pack**

| 10207F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 71.83 | 38.80 | Rosuzet Composite Pack [MK] |

**rosuvastatin 10 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack**

| 10208G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 69.32 | 38.80 | Rosuzet Composite Pack [MK] |

**rosuvastatin 20 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack**

| 10201X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 70.33 | 38.80 | Rosuzet Composite Pack [MK] |

## ▪ ROSUVASTATIN (&) EZETIMIBE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***4068***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4085***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4086***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4069***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4096***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4120***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4121***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be

documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4097***

Hypercholesterolaemia

**Clinical criteria:**

- Patient must have homozygous familial hypercholesterolaemia, **AND**
- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

**Authority required (STREAMLINED)**

***4147***

Hypercholesterolaemia

**Clinical criteria:**

- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs), **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

**rosuvastatin 5 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack**

| 10204C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 68.52 | 38.80 | Rosuzet Composite Pack [MK] |

*HMG CoA reductase inhibitors, other combinations*

## ▪ AMLODIPINE + ATORVASTATIN

**Restricted benefit**

Hypertension

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
- Patient must be currently receiving treatment with a dihydropyridine calcium channel blocker.

**Restricted benefit**

Angina

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
- Patient must be currently receiving treatment with a dihydropyridine calcium channel blocker.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
- Patient must be one in whom blood pressure is inadequately controlled with other classes of antihypertensive agents, **AND**
- The treatment must be appropriate for use as adjunctive therapy with a dihydropyridine calcium channel blocker.

**Restricted benefit**

Angina

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
- Patient must have angina which is inadequately controlled with other classes of anti-anginal agents, **AND**
- The treatment must be appropriate for use as adjunctive therapy with a dihydropyridine calcium channel blocker.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
- Patient must be intolerant of the side effects of other classes of antihypertensive agents, **AND**
- Patient must be one in whom replacement therapy with a dihydropyridine calcium channel blocker would be appropriate.

**Restricted benefit**

Angina

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
- Patient must be intolerant of the side effects of other classes of anti-anginal agents, **AND**
- Patient must be one in whom replacement therapy with a dihydropyridine calcium channel blocker would be appropriate.

**amlodipine 10 mg + atorvastatin 80 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9056P NP | 1 | 5 | .. | 17.21 | 18.42 | [a] APO-Amlodipine/Atorvastatin 10/80 [TX]<br>[a] Cadivast 10/80 [AF] | [a] Blooms the Chemist Amlodipine/Atorvastatin 10/80 [IB]<br>[a] Caduet 10/80 [PF] |

**amlodipine 10 mg + atorvastatin 20 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9054M NP | 1 | 5 | .. | 14.93 | 16.14 | [a] APO-Amlodipine/Atorvastatin 10/20 [TX]<br>[a] Cadivast 10/20 [AF] | [a] Blooms the Chemist Amlodipine/Atorvastatin 10/20 [IB]<br>[a] Caduet 10/20 [PF] |

**amlodipine 5 mg + atorvastatin 20 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9050H NP | 1 | 5 | .. | 14.24 | 15.45 | [a] APO-Amlodipine/Atorvastatin 5/20 [TX]<br>[a] Cadivast 5/20 [AF] | [a] Blooms the Chemist Amlodipine/Atorvastatin 5/20 [IB]<br>[a] Caduet 5/20 [PF] |

**amlodipine 5 mg + atorvastatin 40 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9051J NP | 1 | 5 | .. | 15.15 | 16.36 | [a] APO-Amlodipine/Atorvastatin 5/40 [TX]<br>[a] Cadivast 5/40 [AF] | [a] Blooms the Chemist Amlodipine/Atorvastatin 5/40 [IB]<br>[a] Caduet 5/40 [PF] |

**amlodipine 5 mg + atorvastatin 80 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9052K NP | 1 | 5 | .. | 16.52 | 17.73 | [a] APO-Amlodipine/Atorvastatin 5/80 [TX]<br>[a] Cadivast 5/80 [AF] | [a] Blooms the Chemist Amlodipine/Atorvastatin 5/80 [IB]<br>[a] Caduet 5/80 [PF] |

**amlodipine 10 mg + atorvastatin 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9053L NP | 1 | 5 | .. | 14.20 | 15.41 | [a] APO-Amlodipine/Atorvastatin 10/10 [TX]<br>[a] Cadivast 10/10 [AF] | [a] Blooms the Chemist Amlodipine/Atorvastatin 10/10 [IB]<br>[a] Caduet 10/10 [PF] |

**amlodipine 5 mg + atorvastatin 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9049G NP | 1 | 5 | .. | 13.51 | 14.72 | [a] APO-Amlodipine/Atorvastatin 5/10 [TX]<br>[a] Cadivast 5/10 [AF] | [a] Blooms the Chemist Amlodipine/Atorvastatin 5/10 [IB]<br>[a] Caduet 5/10 [PF] |

**amlodipine 10 mg + atorvastatin 40 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9055N NP | 1 | 5 | .. | 15.84 | 17.05 | [a] APO-Amlodipine/Atorvastatin 10/40 [TX]<br>[a] Cadivast 10/40 [AF] | [a] Blooms the Chemist Amlodipine/Atorvastatin 10/40 [IB]<br>[a] Caduet 10/40 [PF] |

# DERMATOLOGICALS

## ANTIFUNGALS FOR DERMATOLOGICAL USE

### ANTIFUNGALS FOR TOPICAL USE

*Antibiotics*

## ▪ NYSTATIN

**Authority required (STREAMLINED)**

***6434***

Fungal or yeast infection

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**nystatin 100 000 units/g cream, 15 g**

| 1698J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 3 | .. | *21.11 | 22.32 | Mycostatin [FM] |

*Imidazole and triazole derivatives*

## ▪ KETOCONAZOLE

**Authority required (STREAMLINED)**

***6434***

Fungal or yeast infection

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**ketoconazole 2% shampoo, 60 mL**

| 1574W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | .. | 21.58 | 22.79 | Nizoral 2% [JT] |

**ketoconazole 2% cream, 30 g**

| 9024Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 2 | .. | 25.63 | 26.84 | Nizoral 2% Cream [JT] |

**ketoconazole 1% shampoo, 100 mL**

| 9025B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | .. | 20.95 | 22.16 | Nizoral 1% [JT] |

## ▪ MICONAZOLE

**Authority required (STREAMLINED)**

***6434***

Fungal or yeast infection

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**miconazole nitrate 2% dusting powder, 30 g**

| 9029F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 2 | .. | 19.32 | 20.53 | Daktarin [JT] |

**miconazole nitrate 2% cream, 30 g**

| 9027D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 2 | .. | 18.59 | 19.80 | Daktarin [JT] |

**miconazole 2% solution, 30 mL**

| 9031H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 2 | .. | 22.56 | 23.77 | Daktarin Tincture [JT] |

**miconazole nitrate 2% cream, 70 g**

| 9028E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | .. | 20.27 | 21.48 | Daktarin [JT] |

*Other antifungals for topical use*

## ▪ TERBINAFINE

**Authority required (STREAMLINED)**

***6434***

Fungal or yeast infection

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**Authority required (STREAMLINED)**

***6412***

Fungal or yeast infection

**Clinical criteria:**

- The condition must be fungal; OR

- The condition must be due to yeast.

**Population criteria:**

- Patient must be 18 years of age or less.

**terbinafine hydrochloride 1% cream, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9160D NP | 2 | 3 | .. | *37.99 | 38.80 | [a] Lamisil [GK] |

## ANTIFUNGALS FOR SYSTEMIC USE

*Antifungals for systemic use*

### ▪ GRISEOFULVIN

**griseofulvin 125 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1460W NP | 1 | 2 | .. | 27.15 | 28.36 | Grisovin [QA] |

**griseofulvin 500 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2982Y NP | 1 | 2 | .. | 28.09 | 29.30 | Grisovin 500 [QA] |

### ▪ TERBINAFINE

**Authority required**

Dermatophyte infection

**Clinical criteria:**

- Patient must have failed to respond to topical treatment.

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**Authority required**

Dermatophyte infection

**Clinical criteria:**

- Patient must have failed to respond to topical treatment, **AND**
- Patient must have failed to respond to griseofulvin.

**Population criteria:**

- Patient must be 18 years of age or less.

**terbinafine 250 mg tablet, 42**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2285G NP | 1 | .. | .. | 30.00 | 31.21 | [a] GenRx Terbinafine [GX] | [a] Lamisil (Novartis Pharmaceuticals Australia Pty Limited) [NV] |
| | | | | | | [a] Sebifin 250 [RA] | [a] Tamsil [RW] |
| | | | | | | [a] Terbinafine AN [EA] | [a] Terbinafine-DRLA [RZ] |
| | | | | | | [a] Terbinafine GH [GQ] | [a] Terbinafine Sandoz [SZ] |
| | | | | | | [a] Tinasil [AF] | |

### ▪ TERBINAFINE

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

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

**Authority required**

Onychomycosis

**Clinical criteria:**

- The condition must be proximal or extensive (greater than 80% nail involvement), **AND**
- Patient must have failed to respond to topical treatment, **AND**
- The condition must be due to dermatophyte infection proven by microscopy and confirmed by an Approved Pathology Provider; OR
- The condition must be due to dermatophyte infection proven by culture and confirmed by an Approved Pathology Provider.

The date of the pathology report must be provided at the time of application and must not be more than 12 months old

**terbinafine 250 mg tablet, 42**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2804N NP | 1 | 1 | .. | 30.00 | 31.21 | [a] GenRx Terbinafine [GX] | [a] Lamisil (Novartis Pharmaceuticals Australia Pty Limited) [NV] |
| | | | | | | [a] Sebifin 250 [RA] | [a] Tamsil [RW] |
| | | | | | | [a] Terbinafine AN [EA] | [a] Terbinafine-DRLA [RZ] |
| | | | | | | [a] Terbinafine GH [GQ] | [a] Terbinafine Sandoz [SZ] |

[a] Tinasil [AF]

# ANTIPSORIATICS

## ANTIPSORIATICS FOR TOPICAL USE

*Tars*

### PREPARED COAL TAR

**coal tar prepared 2% foam, 100 g**

| 10225E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 2 | .. | 34.27 | 35.48 | Scytera [RZ] |

**prepared coal tar 1% w/w lotion, 100 mL**

| 8864M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 2 | .. | 33.11 | 34.32 | Exorex [GN] |

*Other antipsoriatics for topical use*

### CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE

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

**Authority required (STREAMLINED)**
***6873***
Chronic stable plaque type psoriasis vulgaris
**Clinical criteria:**
- The condition must be inadequately controlled by potent topical corticosteroid monotherapy, **AND**
- Patient must require more than 30 grams of product per month.

**calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% gel, 60 g**

| 10075G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | .. | 63.11 | 38.80 | Daivobet 50/500 gel [LO] |

### CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE

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

**Restricted benefit**
Chronic stable plaque type psoriasis vulgaris
**Clinical criteria:**
- The condition must be inadequately controlled by potent topical corticosteroid monotherapy.

**calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% ointment, 30 g**

| 9494Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | .. | 37.10 | 38.31 | [a] Calcipotriol/Betamethasone Sandoz 50/500 [SZ] | [a] Daivobet [LO] |

**calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% gel, 30 g**

| 5276Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | .. | 37.10 | 38.31 | Daivobet 50/500 gel [LO] |

**calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% foam, 60 g**

| 11091R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | .. | 83.33 | 38.80 | Enstilar [LO] |

## ANTIPSORIATICS FOR SYSTEMIC USE

*Retinoids for treatment of psoriasis*

### ACITRETIN

**Caution** This drug is a potent teratogen - pregnancy should be avoided for at least two years after cessation of therapy.
**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Authority required (STREAMLINED)**
***5789***
Severe intractable psoriasis
**Authority required (STREAMLINED)**

***5727***
Severe disorders of keratinisation

**acitretin 25 mg capsule, 100**

| 2020H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 207.38 | 38.80 | [a] Neotigason [UA]<br>[a] ZETIN [RW] | [a] Novatin [TX] |

**acitretin 10 mg capsule, 100**

| 2019G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 107.34 | 38.80 | [a] Neotigason [UA]<br>[a] ZETIN [RW] | [a] Novatin [TX] |

# ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

## CHEMOTHERAPEUTICS FOR TOPICAL USE

*Sulfonamides*

### SILVER SULFADIAZINE

**Restricted benefit**
Infection
Treatment Phase: Prevention and treatment
**Clinical criteria:**

- The condition must be in partial or full skin thickness loss due to burns; OR
- The condition must be in partial or full skin thickness loss due to epidermolysis bullosa.

**Restricted benefit**
Stasis ulcers

**silver sulfadiazine 1% cream, 50 g**

| 9479X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | .. | .. | 21.62 | 22.83 | Flamazine [SN] |

# CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

## CORTICOSTEROIDS, PLAIN

*Corticosteroids, weak (group I)*

### HYDROCORTISONE ACETATE

**Restricted benefit**
Corticosteroid-responsive dermatoses

**hydrocortisone acetate 1% cream, 50 g**

| 2881P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | .. | 12.95 | 14.16 | [a] Cortic-DS 1% [FM] |
| | | | [B]2.35 | 15.30 | 14.16 | [a] Sigmacort [QA] |

**hydrocortisone acetate 1% ointment, 50 g**

| 2882Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | .. | 12.95 | 14.16 | [a] Cortic-DS 1% [FM] |
| | | | [B]2.35 | 15.30 | 14.16 | [a] Sigmacort [QA] |

### HYDROCORTISONE ACETATE

**Restricted benefit**
Corticosteroid-responsive dermatoses

**hydrocortisone acetate 1% cream, 50 g**

| 5113D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | ‡1 | .. | .. | 12.95 | 14.16 | [a] Cortic-DS 1% [FM] |
| | | | [B]2.35 | 15.30 | 14.16 | [a] Sigmacort [QA] |

**hydrocortisone acetate 1% ointment, 50 g**

| 5114E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | ‡1 | .. | .. | 12.95 | 14.16 | [a] Cortic-DS 1% [FM] |
| | | | [B]2.35 | 15.30 | 14.16 | [a] Sigmacort [QA] |

*Corticosteroids, moderately potent (group II)*

### TRIAMCINOLONE

**Restricted benefit**
Corticosteroid-responsive dermatoses

**triamcinolone acetonide 0.02% ointment, 100 g**

| 2118L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *18.03 | 19.24 | [a] Tricortone [FM] |
| | | | [B]3.28 | *21.31 | 19.24 | [a] Aristocort 0.02% [QA] |

**triamcinolone acetonide 0.02% cream, 100 g**

| 2117K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *18.03 | 19.24 | [a] Tricortone [FM] |
| | | | [B]3.28 | *21.31 | 19.24 | [a] Aristocort 0.02% [QA] |

*Corticosteroids, potent (group III)*

## ▪ BETAMETHASONE DIPROPIONATE

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Corticosteroid-responsive dermatoses

**betamethasone (as dipropionate) 0.05% cream, 15 g**

| 1115Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 16.93 | 18.14 | [a] Eleuphrat [FR] |
| | | | [B]2.45 | 19.38 | 18.14 | [a] Diprosone [MK] |

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

| 1119X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 16.93 | 18.14 | [a] Eleuphrat [FR] |
| | | | [B]2.45 | 19.38 | 18.14 | [a] Diprosone [MK] |

## ▪ BETAMETHASONE DIPROPIONATE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6232***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 10-20% of the patient's body surface area.

**betamethasone (as dipropionate) 0.05% cream, 15 g**

| 10824Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *22.77 | 23.98 | [a] Eleuphrat [FR] |
| | | | [B]4.90 | *27.67 | 23.98 | [a] Diprosone [MK] |

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

| 10795E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *22.77 | 23.98 | [a] Eleuphrat [FR] |
| | | | [B]4.90 | *27.67 | 23.98 | [a] Diprosone [MK] |

## ▪ BETAMETHASONE DIPROPIONATE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6246***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 20-40% of the patient's body surface area.

**betamethasone (as dipropionate) 0.05% cream, 15 g**

| 10800K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *34.47 | 35.68 | [a] Eleuphrat [FR] |
| | | | [B]9.80 | *44.27 | 35.68 | [a] Diprosone [MK] |

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

| 10820L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *34.47 | 35.68 | [a] Eleuphrat [FR] |
| | | | [B]9.80 | *44.27 | 35.68 | [a] Diprosone [MK] |

## ▪ BETAMETHASONE DIPROPIONATE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6218***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**betamethasone (as dipropionate) 0.05% cream, 15 g**

| 10813D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 6 | 5 | .. | *46.15 | 38.80 | [a] Eleuphrat [FR] |
| | | | [B]14.70 | *60.85 | 38.80 | [a] Diprosone [MK] |

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

| 10821M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 6 | 5 | .. | *46.15 | 38.80 | [a] Eleuphrat [FR] |
| | | | [B]14.70 | *60.85 | 38.80 | [a] Diprosone [MK] |

## ▪ BETAMETHASONE DIPROPIONATE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6263***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

**betamethasone (as dipropionate) 0.05% cream, 15 g**

| 10801L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *57.79 | 38.80 | [a] Eleuphrat [FR] |
| | | | [B]19.60 | *77.39 | 38.80 | [a] Diprosone [MK] |

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

| 10816G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *57.79 | 38.80 | [a] Eleuphrat [FR] |
| | | | [B]19.60 | *77.39 | 38.80 | [a] Diprosone [MK] |

## ▪ BETAMETHASONE DIPROPIONATE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6231***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover >80% of the patient's body surface area.

**betamethasone (as dipropionate) 0.05% cream, 15 g**

| 10802M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 10 | 5 | .. | *69.45 | 38.80 | [a] Eleuphrat [FR] |
| | | | [B]24.50 | *93.95 | 38.80 | [a] Diprosone [MK] |

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

| 10823P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 10 | 5 | .. | *69.45 | 38.80 | [a] Eleuphrat [FR] |
| | | | [B]24.50 | *93.95 | 38.80 | [a] Diprosone [MK] |

## ▪ BETAMETHASONE VALERATE

**Restricted benefit**

Corticosteroid-responsive dermatoses

**betamethasone (as valerate) 0.02% cream, 100 g**

| 2812B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *26.57 | 27.78 | [a] Antroquoril [FR] |
| | | | | | | [b] Cortival 1/5 [FM] |
| | | | [B]4.00 | *30.57 | 27.78 | [a] Celestone-M [MK] |
| | | | [B]5.98 | *32.55 | 27.78 | [b] Betnovate 1/5 [QA] |

## ▪ BETAMETHASONE VALERATE

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Corticosteroid-responsive dermatoses

**betamethasone (as valerate) 0.05% cream, 15 g**

| 2813C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 12.82 | 14.03 | [a] Cortival 1/2 [FM] |
| | | | [B]2.56 | 15.38 | 14.03 | [a] Betnovate 1/2 [QA] |

## ▪ BETAMETHASONE VALERATE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6232***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 10-20% of the patient's body surface area.

**betamethasone (as valerate) 0.05% cream, 15 g**

| 10799J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *14.55 | 15.76 | [a] Cortival 1/2 [FM] |
| | | | [B]5.12 | *19.67 | 15.76 | [a] Betnovate 1/2 [QA] |

## ▪ BETAMETHASONE VALERATE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6246***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 20-40% of the patient's body surface area.

**betamethasone (as valerate) 0.05% cream, 15 g**

| 10794D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *18.03 | 19.24 | [a] Cortival 1/2 [FM] |
| | | | [B]10.24 | *28.27 | 19.24 | [a] Betnovate 1/2 [QA] |

## ▪ BETAMETHASONE VALERATE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6218***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**betamethasone (as valerate) 0.05% cream, 15 g**

| 10808W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 6 | 5 | .. | *21.49 | 22.70 | [a] Cortival 1/2 [FM] |
| | | | [B]15.36 | *36.85 | 22.70 | [a] Betnovate 1/2 [QA] |

## ▪ BETAMETHASONE VALERATE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6263***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

**betamethasone (as valerate) 0.05% cream, 15 g**

| 10807T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *24.91 | 26.12 | [a] Cortival 1/2 [FM] |
| | | | [B]20.48 | *45.39 | 26.12 | [a] Betnovate 1/2 [QA] |

## ▪ BETAMETHASONE VALERATE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6231***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover >80% of the patient's body surface area.

**betamethasone (as valerate) 0.05% cream, 15 g**

| 10810Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 10 | 5 | .. | *28.35 | 29.56 | [a] Cortival 1/2 [FM] |
| | | | [B]25.60 | *53.95 | 29.56 | [a] Betnovate 1/2 [QA] |

## ▪ METHYLPREDNISOLONE

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Corticosteroid-responsive dermatoses

**methylprednisolone aceponate 0.1% cream, 15 g**

| 8054X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 17.66 | 18.87 | Advantan [BN] |

**methylprednisolone aceponate 0.1% ointment, 15 g**

| 8055Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 17.66 | 18.87 | Advantan [BN] |

**methylprednisolone aceponate 0.1% ointment: fatty, 15 g**

| 8128T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 17.66 | 18.87 | Advantan [BN] |

## ▪ METHYLPREDNISOLONE

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Eczema

**methylprednisolone aceponate 0.1% lotion, 20 g**

| 8618N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 18.25 | 19.46 | Advantan [BN] |

## ▪ METHYLPREDNISOLONE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6232***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 10-20% of the patient's body surface area.

**methylprednisolone aceponate 0.1% cream, 15 g**

| 10842P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *24.23 | 25.44 | Advantan [BN] |

**methylprednisolone aceponate 0.1% lotion, 20 g**

| 10856J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *25.41 | 26.62 | Advantan [BN] |

**methylprednisolone aceponate 0.1% ointment, 15 g**

| 10846W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *24.23 | 25.44 | Advantan [BN] |

**methylprednisolone aceponate 0.1% ointment: fatty, 15 g**

| 10848Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *24.23 | 25.44 | Advantan [BN] |

## ▪ METHYLPREDNISOLONE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6246***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 20-40% of the patient's body surface area.

**methylprednisolone aceponate 0.1% cream, 15 g**

| 10855H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *37.39 | 38.60 | Advantan [BN] |

**methylprednisolone aceponate 0.1% lotion, 20 g**

| 10838K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 5 | .. | *32.56 | 33.77 | Advantan [BN] |

**methylprednisolone aceponate 0.1% ointment, 15 g**

| 10836H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *37.39 | 38.60 | Advantan [BN] |

**methylprednisolone aceponate 0.1% ointment: fatty, 15 g**

| 10840M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *37.39 | 38.60 | Advantan [BN] |

## ▪ METHYLPREDNISOLONE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6231***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover >80% of the patient's body surface area.

**methylprednisolone aceponate 0.1% cream, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10833E NP | 10 | 5 | .. | *76.75 | 38.80 | Advantan [BN] |

**methylprednisolone aceponate 0.1% lotion, 20 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10830B NP | 5 | 5 | .. | *46.90 | 38.80 | Advantan [BN] |

**methylprednisolone aceponate 0.1% ointment, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10845T NP | 10 | 5 | .. | *76.75 | 38.80 | Advantan [BN] |

**methylprednisolone aceponate 0.1% ointment: fatty, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10843Q NP | 10 | 5 | .. | *76.75 | 38.80 | Advantan [BN] |

## ▪ METHYLPREDNISOLONE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6218***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**methylprednisolone aceponate 0.1% cream, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10835G NP | 6 | 5 | .. | *50.53 | 38.80 | Advantan [BN] |

**methylprednisolone aceponate 0.1% ointment, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10853F NP | 6 | 5 | .. | *50.53 | 38.80 | Advantan [BN] |

**methylprednisolone aceponate 0.1% ointment: fatty, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10844R NP | 6 | 5 | .. | *50.53 | 38.80 | Advantan [BN] |

## ▪ METHYLPREDNISOLONE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6263***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

**methylprednisolone aceponate 0.1% cream, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10851D NP | 8 | 5 | .. | *63.63 | 38.80 | Advantan [BN] |

**methylprednisolone aceponate 0.1% ointment, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10834F NP | 8 | 5 | .. | *63.63 | 38.80 | Advantan [BN] |

**methylprednisolone aceponate 0.1% ointment: fatty, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10839L NP | 8 | 5 | .. | *63.63 | 38.80 | Advantan [BN] |

## ▪ METHYLPREDNISOLONE

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

**Authority required (STREAMLINED)**
***6263***
Corticosteroid-responsive dermatoses
**Clinical criteria:**
- The condition must cover 60-80% of the patient's body surface area.

**Authority required (STREAMLINED)**
***6218***
Corticosteroid-responsive dermatoses
**Clinical criteria:**
- The condition must cover 40-60% of the patient's body surface area.

### methylprednisolone aceponate 0.1% lotion, 20 g

| 10852E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *39.75 | 38.80 | Advantan [BN] |

## ▪ MOMETASONE

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

**Restricted benefit**
Corticosteroid-responsive dermatoses

### mometasone furoate 0.1% cream, 15 g

| 1913Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 14.40 | 15.61 | [a] Momasone [QA] | [a] Novasone [AF] |
| | | | [B]3.53 | 17.93 | 15.61 | [a] Elocon Alcohol Free [MK] | |

### mometasone furoate 0.1% lotion, 30 mL

| 8043H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 16.32 | 17.53 | [a] Momasone [QA]<br>[a] Zatamil [EO] | [a] Novasone [AF] |
| | | | [B]3.53 | 19.85 | 17.53 | [a] Elocon [MK] | |

### mometasone furoate 0.1% ointment, 15 g

| 1915T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 14.40 | 15.61 | [a] Momasone [QA]<br>[a] Zatamil [EO] | [a] Novasone [AF] |
| | | | [B]3.53 | 17.93 | 15.61 | [a] Elocon [MK] | |

## ▪ MOMETASONE

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

**Authority required (STREAMLINED)**
***6232***
Corticosteroid-responsive dermatoses
**Clinical criteria:**
- The condition must cover 10-20% of the patient's body surface area.

### mometasone furoate 0.1% cream, 15 g

| 10827W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *17.71 | 18.92 | [a] Momasone [QA] | [a] Novasone [AF] |
| | | | [B]7.06 | *24.77 | 18.92 | [a] Elocon Alcohol Free [MK] | |

### mometasone furoate 0.1% lotion, 30 mL

| 10819K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *21.55 | 22.76 | [a] Momasone [QA]<br>[a] Zatamil [EO] | [a] Novasone [AF] |
| | | | [B]7.06 | *28.61 | 22.76 | [a] Elocon [MK] | |

**mometasone furoate 0.1% ointment, 15 g**

| 10812C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *17.71 | 18.92 | [a] Momasone [QA]<br>[a] Zatamil [EO] | [a] Novasone [AF] |
| | | | [B]7.06 | *24.77 | 18.92 | [a] Elocon [MK] | |

## ▪ MOMETASONE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6246***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 20-40% of the patient's body surface area.

**mometasone furoate 0.1% cream, 15 g**

| 10809X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *24.35 | 25.56 | [a] Momasone [QA] | [a] Novasone [AF] |
| | | | [B]14.12 | *38.47 | 25.56 | [a] Elocon Alcohol Free [MK] | |

**mometasone furoate 0.1% lotion, 30 mL**

| 10826T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 3 | 5 | .. | *26.77 | 27.98 | [a] Momasone [QA]<br>[a] Zatamil [EO] | [a] Novasone [AF] |
| | | | [B]10.59 | *37.36 | 27.98 | [a] Elocon [MK] | |

**mometasone furoate 0.1% ointment, 15 g**

| 10814E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *24.35 | 25.56 | [a] Momasone [QA]<br>[a] Zatamil [EO] | [a] Novasone [AF] |
| | | | [B]14.12 | *38.47 | 25.56 | [a] Elocon [MK] | |

## ▪ MOMETASONE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6218***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**mometasone furoate 0.1% cream, 15 g**

| 10815F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 6 | 5 | .. | *30.97 | 32.18 | [a] Momasone [QA] | [a] Novasone [AF] |
| | | | [B]21.18 | *52.15 | 32.18 | [a] Elocon Alcohol Free [MK] | |

**mometasone furoate 0.1% ointment, 15 g**

| 10828X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 6 | 5 | .. | *30.97 | 32.18 | [a] Momasone [QA]<br>[a] Zatamil [EO] | [a] Novasone [AF] |
| | | | [B]21.18 | *52.15 | 32.18 | [a] Elocon [MK] | |

## ▪ MOMETASONE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6263***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

**mometasone furoate 0.1% cream, 15 g**

| 10818J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *37.55 | 38.76 | [a] Momasone [QA] | [a] Novasone [AF] |
| | | | [B]28.24 | *65.79 | 38.76 | [a] Elocon Alcohol Free [MK] | |

**mometasone furoate 0.1% ointment, 15 g**

| 10793C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *37.55 | 38.76 | [a] Momasone [QA]<br>[a] Zatamil [EO] | [a] Novasone [AF] |
| | | | [B]28.24 | *65.79 | 38.76 | [a] Elocon [MK] | |

## ▪ MOMETASONE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6231***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover >80% of the patient's body surface area.

**mometasone furoate 0.1% cream, 15 g**

| 10792B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 10 | 5 | .. | *44.15 | 38.80 | [a] Momasone [QA] | [a] Novasone [AF] |
| | | | [B]35.30 | *79.45 | 38.80 | [a] Elocon Alcohol Free [MK] | |

**mometasone furoate 0.1% lotion, 30 mL**

| 10804P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 5 | 5 | .. | *37.25 | 38.46 | [a] Momasone [QA]<br>[a] Zatamil [EO] | [a] Novasone [AF] |
| | | | [B]17.65 | *54.90 | 38.46 | [a] Elocon [MK] | |

**mometasone furoate 0.1% ointment, 15 g**

| 10791Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 10 | 5 | .. | *44.15 | 38.80 | [a] Momasone [QA]<br>[a] Zatamil [EO] | [a] Novasone [AF] |
| | | | [B]35.30 | *79.45 | 38.80 | [a] Elocon [MK] | |

## ▪ MOMETASONE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6263***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

**Authority required (STREAMLINED)**

***6218***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**mometasone furoate 0.1% lotion, 30 mL**

| 10805Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *32.03 | 33.24 | [a] Momasone [QA]<br>[a] Zatamil [EO] | [a] Novasone [AF] |
| | | | [B]14.12 | *46.15 | 33.24 | [a] Elocon [MK] | |

*Corticosteroids, very potent (group IV)*

## ▪ CLOBETASOL

**Authority required (STREAMLINED)**

***5461***

Moderate to severe scalp psoriasis

**Clinical criteria:**

- The condition must be inadequately controlled with either a vitamin D analogue or potent topical corticosteroid as monotherapy; OR
- The condition must be inadequately controlled with combination use of a vitamin D analogue and potent topical corticosteroid.

**Population criteria:**

- Patient must be aged 18 years or older.

**clobetasol propionate 0.05% shampoo, 125 mL**

10080M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 48.81 | 38.80 | Clobex [GA] |

# ANTI-ACNE PREPARATIONS

## ANTI-ACNE PREPARATIONS FOR TOPICAL USE

*Retinoids for topical use in acne*

### ADAPALENE + BENZOYL PEROXIDE

**Restricted benefit**

Severe acne vulgaris

Treatment Phase: Acute treatment

**Clinical criteria:**

- The treatment must in combination with an oral antibiotic.

**adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g**

8954G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 36.29 | 37.50 | Epiduo [GA] |

### ADAPALENE + BENZOYL PEROXIDE

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Severe acne vulgaris

**Clinical criteria:**

- The treatment must be maintenance therapy.

**adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g**

8955H

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 3 | .. | 36.29 | 37.50 | Epiduo [GA] |

## ANTI-ACNE PREPARATIONS FOR SYSTEMIC USE

*Retinoids for treatment of acne*

### ISOTRETINOIN

**Caution** This drug causes birth defects.

This drug has been reported to cause other frequent and potentially serious toxicity.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Authority required (STREAMLINED)**

***5224***

Severe cystic acne

**Clinical criteria:**

- The condition must be unresponsive to other therapy.

**isotretinoin 20 mg capsule, 60**

2592K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 47.99 | 38.80 | [a] APO-Isotretinoin [TX]<br>[a] Isotretinoin AN [EA]<br>[a] Oratane [RF]<br>[a] Rocta 20 [RW] | [a] Dermatane [ER]<br>[a] Isotretinoin SCP 20 [CR]<br>[a] Roaccutane [RO] |

**isotretinoin 10 mg capsule, 60**

2591J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 34.77 | 35.98 | [a] APO-Isotretinoin [TX]<br>[a] Isotretinoin AN [EA]<br>[a] Roaccutane [RO] | [a] Dermatane [ER]<br>[a] Oratane [RF]<br>[a] Rocta 10 [RW] |

**isotretinoin 40 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2549E | 1 | 3 | .. | 44.40 | 38.80 | [a] Dermatane [ER] | [a] Oratane [RF] |

# OTHER DERMATOLOGICAL PREPARATIONS

## OTHER DERMATOLOGICAL PREPARATIONS

*Agents for dermatitis, excluding corticosteroids*

### PIMECROLIMUS

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

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

**Authority required (STREAMLINED)**

***5482***

Atopic dermatitis

**Population criteria:**

- Patient must be at least 3 months of age.

**Clinical criteria:**

- The condition must be on the patient's face; OR
- The condition must be on the patient's eyelid, **AND**
- Patient must have 1 or more of the following contraindications to topical corticosteroids: (i) perioral dermatitis; (ii) periorbital dermatitis; (iii) rosacea; (iv) epidermal atrophy; (v) dermal atrophy; (vi) allergy to topical corticosteroids; (vii) cataracts; (viii) glaucoma; (ix) raised intraocular pressure, **AND**
- Patient must not receive more than two 15 g packs of PBS-subsidised pimecrolimus per 6-month period.

**Authority required (STREAMLINED)**

***5472***

Atopic dermatitis

Treatment Phase: Short-term (up to 3 weeks) intermittent treatment

**Population criteria:**

- Patient must be at least 3 months of age.

**Clinical criteria:**

- The condition must be on the patient's face; OR
- The condition must be on the patient's eyelid, **AND**
- Patient must have failed to achieve satisfactory disease control with intermittent topical corticosteroid therapy, **AND**
- The condition must have been initially diagnosed more than three months prior to this treatment, **AND**
- Patient must not receive more than two 15 g packs of PBS-subsidised pimecrolimus per 6-month period.

Failure to achieve satisfactory disease control with intermittent topical corticosteroid therapy is manifest by:

(i) failure of the facial skin to clear despite at least 2 weeks of topical hydrocortisone 1% applied every day; or

(ii) failure of the facial skin to clear despite at least 1 week of a moderate or potent topical corticosteroid applied every day; or

(iii) clearing of the facial skin with at least 2 weeks of topical hydrocortisone 1% applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions; or

(iv) clearing of the facial skin with at least 1 week of a moderate or potent topical corticosteroid applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions

**pimecrolimus 1% cream, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8802G | ‡1 | 1 | .. | 33.70 | 34.91 | Elidel [HM] |

*Other dermatologicals*

### DAPSONE

**Note Shared Care Model**:

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

**dapsone 100 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1272Y NP | 1 | 1 | .. | 353.02 | 38.80 | Link Medical Products Pty Ltd [LM] |

**dapsone 25 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8801F NP | 1 | 1 | .. | 288.57 | 38.80 | Link Medical Products Pty Ltd [LM] |

## ▪ IMIQUIMOD

**Note** The patient or carer must be able to understand and administer the imiquimod dosing regimen.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Treatment of recurrent (previously treated) lesions will not be authorised.
**Note** Pharmaceutical benefits that have the form imiquimod single use sachets and pharmaceutical benefits that have the form imiquimod multi-use pump are equivalent for the purposes of substitution.

**Authority required**
Superficial basal cell carcinoma
**Clinical criteria:**

- The condition must be previously untreated, **AND**
- The condition must be confirmed by biopsy, **AND**
- Patient must have normal immune function, **AND**
- The condition must not be suitable for treatment with surgical excision; OR
- The condition must not be suitable for treatment with cryotherapy; OR
- The condition must not be suitable for treatment with curettage with diathermy, **AND**
- Patient must require topical drug therapy.

The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.

**imiquimod 5% cream, 2 x 2 g**

2637T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | [B]4.55 | 91.17 | 38.80 | [a] Aldara Pump [IA] |

**imiquimod 5% cream, 12 x 250 mg sachets**

2546B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 86.62 | 38.80 | [a] Aldiq [QA] | [a] APO-Imiquimod [TX] |
| | | [B]2.28 | 88.90 | 38.80 | [a] Aldara [IA] | |

# ▪ GENITO URINARY SYSTEM AND SEX HORMONES

## ▪ OTHER GYNECOLOGICALS

### CONTRACEPTIVES FOR TOPICAL USE

*Intrauterine contraceptives*

## ▪ LEVONORGESTREL

**Restricted benefit**
Contraception
**Restricted benefit**
Idiopathic menorrhagia
**Clinical criteria:**

- The treatment must be in a patient where oral treatments are ineffective.

**Restricted benefit**
Idiopathic menorrhagia
**Clinical criteria:**

- The treatment must be in a patient where oral treatments are contraindicated.

**levonorgestrel 52 mg intrauterine drug delivery system, 1 system**

8633J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 242.55 | 38.80 | Mirena [BN] |

NP

### OTHER GYNECOLOGICALS

*Prolactine inhibitors*

## ▪ BROMOCRIPTINE

**Restricted benefit**
Prevention of the onset of lactation
**Clinical criteria:**

- The treatment must occur in the puerperium, **AND**
- The treatment must be for medical reasons.

**bromocriptine 2.5 mg tablet, 30**

1444B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 21.96 | 23.17 | Parlodel [SZ] |

NP

## ▪ BROMOCRIPTINE

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

Acromegaly

**Restricted benefit**

Parkinson disease

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom surgery is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had surgery for this condition with incomplete resolution.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom radiotherapy is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had radiotherapy for this condition with incomplete resolution.

**bromocriptine 2.5 mg tablet, 30**

1443Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *32.83 | 34.04 | Parlodel [SZ] |

## ▪ CABERGOLINE

**Restricted benefit**

Prevention of the onset of lactation

**Clinical criteria:**

- The treatment must occur in the puerperium, **AND**
- The treatment must be for medical reasons.

**cabergoline 500 microgram tablet, 2**

8115D

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 24.45 | 25.66 | [a] APO-Cabergoline [TX] | [a] Dostinex [PF] |

## ▪ CABERGOLINE

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom surgery is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had surgery for this condition with incomplete resolution.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom radiotherapy is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had radiotherapy for this condition with incomplete resolution.

**cabergoline 500 microgram tablet, 8**

8114C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 64.55 | 38.80 | [a] APO-Cabergoline [TX] | [a] Dostinex [PF] |

## ▪ QUINAGOLIDE

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom surgery is not indicated.

**Restricted benefit**
Pathological hyperprolactinaemia
**Clinical criteria:**
- Patient must have had surgery for this condition with incomplete resolution.

**Restricted benefit**
Pathological hyperprolactinaemia
**Clinical criteria:**
- Patient must be one in whom radiotherapy is not indicated.

**Restricted benefit**
Pathological hyperprolactinaemia
**Clinical criteria:**
- Patient must have had radiotherapy for this condition with incomplete resolution.

**quinagolide 25 microgram tablet [3 tablets] (&) quinagolide 50 microgram tablet [3 tablets], 6**

| 8860H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 15.26 | 16.47 | Norprolac [FP] |

**quinagolide 75 microgram tablet, 30**

| 8822H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 52.76 | 38.80 | Norprolac [FP] |

# SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

## HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE

*Progestogens and estrogens, fixed combinations*

### LEVONORGESTREL + ETHINYLOESTRADIOL

**levonorgestrel 125 microgram + ethinyloestradiol 50 microgram tablet [21] (&) inert substance tablet [7], 4 x 28**

| 1456P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 18.81 | 20.02 | Microgynon 50 ED [BN] |

**ethinyloestradiol 20 microgram + levonorgestrel 100 microgram tablet [84] (&) inert substance tablet [28], 112 [4 x 28]**

| 2416E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 17.20 | 18.41 | Femme-Tab ED 20/100 [AE] |

**levonorgestrel 150 microgram + ethinyloestradiol 30 microgram tablet [21] (&) inert substance tablet [7], 4 x 28**

| 1394J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 17.20 | 18.41 | [a] Monofeme 28 [FZ]<br>[b] Eleanor 150/30 ED [EA]<br>[b] Femme-Tab ED 30/150 [AE]<br>[b] Micronelle 30 ED [TX] | [b] Evelyn 150/30 ED [GQ]<br>[b] Lenest 30 ED [AF] |
| | | | [B]2.21 | 19.41 | 18.41 | [b] Levlen ED [SY] | |
| | | | [B]9.02 | 26.22 | 18.41 | [b] Microgynon 30 ED [BN] | |
| | | | [B]11.56 | 28.76 | 18.41 | [a] Nordette 28 [PF] | |

### NORETHISTERONE + ETHINYLOESTRADIOL

**norethisterone 500 microgram + ethinyloestradiol 35 microgram tablet [21] (&) inert substance tablet [7], 4 x 28**

| 2774B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 19.82 | 21.03 | [a] Norimin 28 Day [FZ] |
| | | | [B]9.78 | 29.60 | 21.03 | [a] Brevinor [PF] |

**norethisterone 1 mg + ethinyloestradiol 35 microgram tablet [21] (&) inert substance tablet [7], 4 x 28**

| 2775C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 19.82 | 21.03 | [a] Norimin-1 28 Day [FZ] |
| | | | [B]9.78 | 29.60 | 21.03 | [a] Brevinor-1 [PF] |

### NORETHISTERONE + MESTRANOL

**norethisterone 1 mg + mestranol 50 microgram tablet [21] (&) inert substance tablet [7], 4 x 28**

| 3179H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 19.82 | 21.03 | Norinyl-1/28 [PF] |

*Progestogens and estrogens, sequential preparations*

## ▪ LEVONORGESTREL + ETHINYLOESTRADIOL

**ethinyloestradiol 30 microgram + levonorgestrel 50 microgram tablet [24] (&) ethinyloestradiol 40 microgram + levonorgestrel 75 microgram tablet [20] (&) ethinyloestradiol 30 microgram + levonorgestrel 125 microgram tablet [40] (&) inert substance tablet [28], 112 [4 x 28]**

| 1392G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 18.81 | 20.02 | [a] Trifeme 28 [FZ] |
| | | | | | | [b] Logynon ED [SY] |
| | | | [B]11.41 | 30.22 | 20.02 | [b] Triquilar ED [BN] |
| | | | [B]13.00 | 31.81 | 20.02 | [a] Triphasil 28 [PF] |

*Progestogens*

## ▪ ETONOGESTREL

**etonogestrel 68 mg implant, 1**

| 8487Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 1 | .. | .. | 193.08 | 38.80 | Implanon NXT [MK] |

## ▪ LEVONORGESTREL

**levonorgestrel 30 microgram tablet, 112 tablets [4 x 28]**

| 2913H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 1 | 2 | .. | 20.10 | 21.31 | Microlut 28 [BN] |

## ▪ MEDROXYPROGESTERONE

**medroxyprogesterone acetate 150 mg/mL injection, 1 mL vial**

| 3118D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 25.22 | 26.43 | [a] Depo-Ralovera [FZ] |
| | | | [B]7.00 | 32.22 | 26.43 | [a] Depo-Provera [PF] |

## ▪ NORETHISTERONE

**norethisterone 350 microgram tablet, 4 x 28**

| 1967M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 19.82 | 21.03 | Noriday 28 Day [PF] |

# ANDROGENS

*3-oxoandrosten (4) derivatives*

## ▪ TESTOSTERONE

**Authority required**

Androgen deficiency

**Clinical criteria:**

- Patient must have an established pituitary or testicular disorder.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Androgen deficiency

**Clinical criteria:**

- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

**Population criteria:**

- Patient must be aged 40 years or older.

**Treatment criteria:**

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

**Authority required**

Micropenis

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Pubertal induction

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Constitutional delay of growth or puberty

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**testosterone 2.5 mg/24 hours patch, 60**

| 8460G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 5 | .. | 88.31 | 38.80 | Androderm [GN] |

**testosterone 5% (50 mg/mL) cream, 50 mL**

| 10378F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 6 | .. | 73.95 | 38.80 | AndroForte 5 [LX] |

**testosterone 1% (12.5 mg/actuation) gel, 2 x 60 actuations**

| 10380H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 4 | .. | 87.70 | 38.80 | Testogel [HB] |

**testosterone 5 mg/24 hours patch, 30**

| 8619P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 5 | .. | 88.31 | 38.80 | Androderm [GN] |

**testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets**

| 8830R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 5 | .. | 87.70 | 38.80 | Testogel [HB] |

**testosterone 2% (30 mg/actuation) solution, 60 actuations**

| 2341F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 5 | .. | 76.76 | 38.80 | Axiron [LY] |

## ▪ TESTOSTERONE ENANTHATE

**Authority required**

Androgen deficiency

**Clinical criteria:**

- Patient must have an established pituitary or testicular disorder.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Androgen deficiency

**Clinical criteria:**

- Patient must not have an established pituitary or testicular disorder, **AND**

- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

**Population criteria:**

- Patient must be aged 40 years or older.

**Treatment criteria:**

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

**Authority required**

Micropenis

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Pubertal induction

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Constitutional delay of growth or puberty

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**testosterone enanthate 250 mg/mL injection, 3 x 1 mL syringes**

2114G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 33.44 | 34.65 | Primoteston Depot [BN] |

## ▪ TESTOSTERONE UNDECANOATE

**Authority required**

Androgen deficiency

**Clinical criteria:**

- Patient must have an established pituitary or testicular disorder.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Androgen deficiency

**Clinical criteria:**

- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

**Population criteria:**

- Patient must be aged 40 years or older.

**Treatment criteria:**

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

**Authority required**

Micropenis

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Pubertal induction

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Constitutional delay of growth or puberty

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**testosterone undecanoate 40 mg capsule, 60**

| 2115H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 36.79 | 38.00 | Andriol Testocaps [MK] |

**testosterone undecanoate 1 g/4 mL injection, 4 mL vial**

| 10205D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 132.86 | 38.80 | Reandron 1000 [BN] |

## ESTROGENS

*Natural and semisynthetic estrogens, plain*

### ▪ OESTRADIOL

**Note Continuing Therapy Only:**

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

**oestradiol 10 microgram modified release pessary, 18**

| 10203B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 33.16 | 34.37 | Vagifem Low [NO] |

**oestradiol valerate 1 mg tablet, 56**

| 1663M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 15.66 | 16.87 | Progynova [BN] |

**oestradiol 2 mg tablet, 56**

| 8274L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 17.29 | 18.50 | Zumenon [GO] |

**oestradiol valerate 2 mg tablet, 56**

| 1664N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 17.59 | 18.80 | Progynova [BN] |

## ▪ OESTRADIOL

**Note** Oestradiol should be used in conjunction with an oral progestogen in women with an intact uterus.

**Note Continuing Therapy Only:**

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

**oestradiol 100 microgram/24 hours patch, 4**

| 8126Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 22.14 | 23.35 | Climara 100 [BN] |

**oestradiol 75 microgram/24 hours patch, 8**

| 8764G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 22.14 | 23.35 | Estradot 75 [SZ] |

**oestradiol 75 microgram/24 hours patch, 4**

| 8486P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 22.14 | 23.35 | Climara 75 [BN] |

**oestradiol 25 microgram/24 hours patch, 4**

| 8485N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 20.37 | 21.58 | Climara 25 [BN] |

**oestradiol 50 microgram/24 hours patch, 8**

| 8140K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 20.37 | 21.58 | Estraderm MX 50 [JU] |

**oestradiol 50 microgram/24 hours patch, 8**

| 8763F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 20.37 | 21.58 | Estradot 50 [SZ] |

**oestradiol 100 microgram/24 hours patch, 8**

| 8312L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 22.14 | 23.35 | Estraderm MX 100 [JU] |

**oestradiol 100 microgram/24 hours patch, 8**

| 8765H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 22.14 | 23.35 | Estradot 100 [SZ] |

**oestradiol 37.5 microgram/24 hours patch, 8**

| 8762E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 20.37 | 21.58 | Estradot 37.5 [SZ] |

**oestradiol 25 microgram/24 hours patch, 8**

| 8311K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 20.37 | 21.58 | Estraderm MX 25 [JU] |

**oestradiol 25 microgram/24 hours patch, 8**

| 8761D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 20.37 | 21.58 | Estradot 25 [SZ] |

**oestradiol 50 microgram/24 hours patch, 4**

| 8125P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 20.37 | 21.58 | Climara 50 [BN] |

**oestradiol 0.1% (1 mg/g) gel, 28 x 1 g sachets**

| 8286D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 20.37 | 21.58 | Sandrena [AS] |

## ▪ OESTRIOL

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

**oestriol 0.1% (1 mg/g) cream, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1781R NP | ‡1 | 1 | .. | 21.56 | 22.77 | Ovestin [AS] |

**oestriol 500 microgram pessary, 15**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1771F NP | ‡1 | 2 | .. | 23.35 | 24.56 | Ovestin Ovula [AS] |

## PROGESTOGENS

*Pregnen (4) derivatives*

## ▪ MEDROXYPROGESTERONE

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

**medroxyprogesterone acetate 5 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2323G NP | 1 | 2 | .. | 19.09 | 20.30 | [a] Ralovera [FZ] |
| | | | [B]6.70 | 25.79 | 20.30 | [a] Provera [PF] |

**medroxyprogesterone acetate 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2321E NP | 1 | 2 | .. | 17.96 | 19.17 | [a] Ralovera [FZ] |
| | | | [B]6.70 | 24.66 | 19.17 | [a] Provera [PF] |

## ▪ MEDROXYPROGESTERONE

**Restricted benefit**
Endometriosis

**medroxyprogesterone acetate 10 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2722G | 1 | 2 | .. | 33.99 | 35.20 | [a] Ralovera [FZ] |
| | | | [B]6.70 | 40.69 | 35.20 | [a] Provera [PF] |

*Estren derivatives*

## ▪ NORETHISTERONE

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

**norethisterone 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2993M NP | 1 | 2 | .. | 33.30 | 34.51 | Primolut N [BN] |

## PROGESTOGENS AND ESTROGENS IN COMBINATION

*Progestogens and estrogens, fixed combinations*

## ▪ OESTRADIOL + DYDROGESTERONE

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

**oestradiol 1 mg + dydrogesterone 5 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10142T NP | 1 | 5 | .. | 21.82 | 23.03 | Femoston-Conti [GO] |

## ▪ OESTRADIOL + NORETHISTERONE ACETATE

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

**oestradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8428N NP | ‡1 | 5 | .. | 22.14 | 23.35 | Estalis continuous 50/250 [SZ] |

**oestradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8427M NP | ‡1 | 5 | .. | 22.14 | 23.35 | Estalis continuous 50/140 [SZ] |

*Progestogens and estrogens, sequential preparations*

## ▪ NORETHISTERONE ACETATE + OESTRADIOL (&) OESTRADIOL

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

**oestradiol 50 microgram/24 hours patch [4] (&) oestradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch [4], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8426L NP | ‡1 | 5 | .. | 22.14 | 23.35 | Estalis sequi 50/250 [SZ] |

**oestradiol 50 microgram/24 hours patch [4] (&) oestradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch [4], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8425K NP | ‡1 | 5 | .. | 22.14 | 23.35 | Estalis sequi 50/140 [SZ] |

## ▪ OESTRADIOL (&) OESTRADIOL + DYDROGESTERONE

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

**oestradiol 2 mg tablet [14] (&) oestradiol 2 mg + dydrogesterone 10 mg tablet [14], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8244X NP | ‡1 | 5 | .. | 21.82 | 23.03 | Femoston 2/10 [GO] |

**oestradiol 1 mg tablet [14] (&) oestradiol 1 mg + dydrogesterone 10 mg tablet [14], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10146B NP | ‡1 | 5 | .. | 21.82 | 23.03 | Femoston 1/10 [GO] |

# GONADOTROPINS AND OTHER OVULATION STIMULANTS

*Gonadotropins*

## ▪ FOLLITROPIN ALFA

**Note** Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

**Note** Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

**Restricted benefit**
Anovulatory infertility

**Note** Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

**Note** Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

**Restricted benefit**
Infertility

**Clinical criteria:**

- The condition must be due to hypogonadotrophic hypogonadism, **AND**
- The treatment must be following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis, **AND**
- The treatment must be administered with human chorionic gonadotrophin.

**follitropin alfa 900 units (65.52 microgram)/1.5 mL injection, 1.5 mL cartridge**

| 8715Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *733.65 | 38.80 | Gonal-f Pen [SG] |

**follitropin alfa 300 units (21.84 microgram)/0.5 mL injection, 0.5 mL cartridge**

| 8713N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 5 | .. | *369.22 | 38.80 | Gonal-f Pen [SG] |

**follitropin alfa 225 units (16.5 microgram)/0.375 mL injection, 5 x 0.375 mL injection devices**

| 10876K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 1 | .. | *1348.21 | 38.80 | Bemfola [FX] |

**follitropin alfa 75 units (5.5 microgram)/0.125 mL injection, 5 x 0.125 mL injection devices**

| 10865W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 1 | .. | *460.33 | 38.80 | Bemfola [FX] |

**follitropin alfa 150 units (11 microgram)/0.25 mL injection, 5 x 0.25 mL injection devices**

| 10877L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 1 | .. | *915.85 | 38.80 | Bemfola [FX] |

**follitropin alfa 450 units (32.76 microgram)/0.75 mL injection, 0.75 mL cartridge**

| 8714P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 5 | .. | *551.44 | 38.80 | Gonal-f Pen [SG] |

## ▪ FOLLITROPIN BETA

**Note** Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

**Note** Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

**Restricted benefit**

Anovulatory infertility

**Note** Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

**Note** Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

**Restricted benefit**

Infertility

**Clinical criteria:**

- The condition must be due to hypogonadotrophic hypogonadism, **AND**
- The treatment must be following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis, **AND**
- The treatment must be administered with human chorionic gonadotrophin.

**follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge**

| 8565T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 5 | .. | *480.55 | 38.80 | Puregon 300 IU/0.36 mL [MK] |

**follitropin beta 900 units/1.08 mL injection, 1.08 mL cartridge**

| 8871X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *924.87 | 38.80 | Puregon 900 IU/1.08 mL [MK] |

**follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge**

| 8566W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *623.69 | 38.80 | Puregon 600 IU/0.72 mL [MK] |

## ▪ HUMAN CHORIONIC GONADOTROPHIN

**Note** Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

**Restricted benefit**

Anovulatory infertility

**Note** Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

**Note** Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

**Note** Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

**Restricted benefit**

Infertility

**Population criteria:**

- Patient must be male.

**Clinical criteria:**

- The condition must be due to hypogonadotrophic hypogonadism.

**Restricted benefit**

Infertility

**Population criteria:**

- Patient must be male.

**Clinical criteria:**

- The condition must be associated with isolated luteinising hormone deficiency.

**Restricted benefit**

Combined deficiency of human growth hormone and gonadotrophins

**Population criteria:**

- Patient must be male.

**Clinical criteria:**

- Patient must be one in whom the absence of secondary sexual characteristics indicates a lag in maturation.

**Restricted benefit**

Hypogonadism or delayed puberty

**Population criteria:**

- Patient must be male, **AND**
- Patient must be aged 16 years or older.

**Clinical criteria:**

- Patient must show clinical evidence of the condition, **AND**
- The treatment must not extend beyond 6 months.

**human chorionic gonadotrophin 1500 units injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack**

11148R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 45.04 | 38.80 | Pregnyl [MK] |

*Ovulation stimulants, synthetic*

## ▪ CLOMIFENE

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Restricted benefit**

Anovulatory infertility

**Restricted benefit**

Patients undergoing in-vitro fertilisation

**clomifene citrate 50 mg tablet, 10**

1211R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 35.52 | 36.73 | Clomid [SW] |

## ANTIANDROGENS

*Antiandrogens, plain*

## ▪ CYPROTERONE

**cyproterone acetate 100 mg tablet, 50**

8019C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 66.87 | 38.80 | [a] ANTERONE 100 [RW]<br>[a] Cyprone 100 [AF]<br>[a] Cyproterone AN [EA]<br>[a] GenRx Cyproterone Acetate [GX] | [a] Cyprocur 100 [QA]<br>[a] Cyprostat-100 [SY]<br>[a] Cyproterone Sandoz [HX]<br>[a] Procur 100 [ED] |
| | | [B]1.41 | 68.28 | 38.80 | [a] Androcur-100 [BN] | |

**cyproterone acetate 50 mg tablet, 50**

1270W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *82.69 | 38.80 | [a] ANTERONE 50 [RW]<br>[a] Cyprone [AF]<br>[a] Cyproterone AN [EA]<br>[a] Cyrotone [ER] | [a] Cyprocur 50 [QA]<br>[a] Cyprostat [SY]<br>[a] Cyproterone Sandoz [HX]<br>[a] GenRx Cyproterone Acetate [GX] |
| | | [B]2.28 | *84.97 | 38.80 | [a] Androcur [BN] | |

## ▪ CYPROTERONE

**Caution** This drug should not be used during pregnancy as it may result in feminisation of the male foetus.

**Authority required (STREAMLINED)**

***5532***
Moderate to severe androgenisation
**Clinical criteria:**
- The condition must not be indicated by acne alone, as this is not a sufficient indication of androgenisation.

**Population criteria:**
- Patient must be female.

**Clinical criteria:**
- Patient must not be pregnant.

**cyproterone acetate 50 mg tablet, 20**

1269T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 25.41 | 26.62 | [a] ANTERONE 50 [RW]<br>[a] Cyprone [AF]<br>[a] Cyproterone AN [EA]<br>[a] GenRx Cyproterone Acetate [GX] | [a] Cyprocur 50 [QA]<br>[a] Cyprostat [SY]<br>[a] Cyproterone Sandoz [HX] |
| | | [B]2.40 | 27.81 | 26.62 | [a] Androcur [BN] | |

## OTHER SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

*Antigonadotropins and similar agents*

### ▪ DANAZOL

**Caution** Pregnancy must be excluded prior to administration of this drug.

**Authority required (STREAMLINED)**
***6293***
Endometriosis
**Clinical criteria:**
- The condition must be visually proven.

**Authority required (STREAMLINED)**
***6285***
Hereditary angio-oedema

**Authority required (STREAMLINED)**
***6259***
Intractable primary menorrhagia
**Clinical criteria:**
- The treatment must be for the short-term (up to 6 months).

**Note** Treatment of this indication is limited to 6 months. See Australian Product Information

**Authority required (STREAMLINED)**
***6242***
Breast disease
**Clinical criteria:**
- The treatment must be for the short-term (up to 6 months), **AND**
- The condition must be severe benign (fibrocystic) breast disease; OR
- The condition must be mastalgia associated with severe symptomatic benign breast disease, **AND**
- The condition must be refractory to treatment with other drugs.

**Note** Treatment of this indication is limited to 6 months. See Australian Product Information

**danazol 100 mg capsule, 100**

1285P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 56.14 | 38.80 | Azol 100 [AF] |

**danazol 200 mg capsule, 100**

1287R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 80.66 | 38.80 | Azol 200 [AF] |

*Progesterone receptor modulators*

### ▪ MIFEPRISTONE (&) MISOPROSTOL

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

**Authority required**
Termination of an intra-uterine pregnancy
**Clinical criteria:**
- The condition must be an intra-uterine pregnancy of up to 63 days of gestation.

**Treatment criteria:**
- Must be treated by a prescriber who is registered with the MS 2 Step Prescribing Program.

**mifepristone 200 mg tablet [1] (&) misoprostol 200 microgram tablet [4], 1 pack**

| 10211K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 311.79 | 38.80 | MS-2 Step [XH] |

# UROLOGICALS

## UROLOGICALS

*Drugs for urinary frequency and incontinence*

### OXYBUTYNIN

**Restricted benefit**

Detrusor overactivity

**oxybutynin hydrochloride 5 mg tablet, 100**

| 8039D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.90 | 16.11 | [a] Ditropan [SW] | [a] Oxybutynin Sandoz [SZ] |

### OXYBUTYNIN

**Restricted benefit**

Detrusor overactivity

**Clinical criteria:**

- Patient must be unable to tolerate oral oxybutynin; OR
- Patient must be unable to swallow oral oxybutynin.

**oxybutynin 3.9 mg/24 hours patch, 8**

| 9454N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 36.14 | 37.35 | Oxytrol [GN] |

### PROPANTHELINE

**Restricted benefit**

Detrusor overactivity

**propantheline bromide 15 mg tablet, 100**

| 1953T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *27.65 | 28.86 | Pro-Banthine [RW] |

*Other urologicals*

### BICARBONATE

**sodium bicarbonate 840 mg capsule, 100**

| 9470K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 17.35 | 18.56 | Sodibic [AS] |

### PHENOXYBENZAMINE

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Phaeochromocytoma

**Restricted benefit**

Neurogenic urinary retention

**phenoxybenzamine hydrochloride 10 mg capsule, 100**

| 1862B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 1103.27 | 38.80 | Dibenyline [GH] |

**phenoxybenzamine hydrochloride 10 mg capsule, 100**

| 9286R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 1103.27 | 38.80 | Dibenzyline [BZ] |

**phenoxybenzamine hydrochloride 10 mg capsule, 30**

| 1166J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 5 | .. | *997.75 | 38.80 | Amdipharm Mercury (Australia) Pty Limited [GH] |

## DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY

*Alpha-adrenoreceptor antagonists*

### ▪ DUTASTERIDE + TAMSULOSIN

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6189***

Benign prostatic hyperplasia

**Clinical criteria:**

- Patient must have lower urinary tract symptoms, **AND**
- Patient must have moderate to severe benign prostatic hyperplasia.

**dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30**

5490Y

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 35.14 | 36.35 | Duodart 500ug/400ug [GK] |

*Testosterone-5-alpha reductase inhibitors*

### ▪ DUTASTERIDE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6202***

Benign prostatic hyperplasia

**Clinical criteria:**

- Patient must have lower urinary tract symptoms, **AND**
- Patient must have moderate to severe benign prostatic hyperplasia, **AND**
- The treatment must be in combination with an alpha-antagonist.

**dutasteride 500 microgram capsule, 30**

5468T

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 30.93 | 32.14 | Avodart [GK] |

# ▪ SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

## ▪ PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

### ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES

*ACTH*

### ▪ TETRACOSACTRIN

**tetracosactrin 1 mg/mL modified release injection, 1 mL ampoule**

2832C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | 5 | .. | *449.95 | 38.80 | Synacthen Depot 1 mg/1 mL [LM] |

*Thyrotropin*

### ▪ THYROTROPIN ALFA

**Restricted benefit**

Ablation of thyroid remnant tissue

**Clinical criteria:**

- Patient must have undergone a thyroidectomy, **AND**
- The treatment must be in combination with radioactive iodine, **AND**
- Patient must not have a known metastatic disease.

**thyrotropin alfa 900 microgram injection, 2 vials**

2700D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 1802.84 | 38.80 | Thyrogen [GZ] |

### POSTERIOR PITUITARY LOBE HORMONES

*Vasopressin and analogues*

## ▪ DESMOPRESSIN

**Authority required (STREAMLINED)**

***5266***

Cranial diabetes insipidus

**desmopressin acetate 200 microgram tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8662X | 3 | 5 | .. | *160.90 | 38.80 | Minirin [FP] |

**desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8711L | 2 | 5 | .. | *144.61 | 38.80 | Minirin Nasal Spray [FP] |

**desmopressin acetate 100 microgram/mL nasal drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2129C | 5 | 5 | .. | *144.75 | 38.80 | Minirin [FP] |

## ▪ DESMOPRESSIN

**Note** Not to be used in preference to enuresis alarms.

**Note** Only one application per six months with no more than twice the maximum quantity will be authorised for the tablets.

**Authority required (STREAMLINED)**

***5413***

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be refractory to an enuresis alarm.

**Authority required (STREAMLINED)**

***5295***

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

**desmopressin acetate 200 microgram tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8663Y NP | 1 | 5 | .. | 61.03 | 38.80 | Minirin [FP] |

## ▪ DESMOPRESSIN

**Caution** Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.

**Note** Not to be used in preference to enuresis alarms.

**Authority required (STREAMLINED)**

***5342***

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be refractory to an enuresis alarm.

**Authority required (STREAMLINED)**

***5267***

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

**desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8712M NP | ‡1 | 5 | .. | 77.85 | 38.80 | Minirin Nasal Spray [FP] |

## ▪ DESMOPRESSIN

**Note** Not to be used in preference to enuresis alarms.

**Note** Only one application per six months will be authorised for the wafers. No more than twice the maximum quantity for the 120 micrograms wafers and no applications for increased maximum quantities for the 240 micrograms wafers will be authorised.

**Authority required (STREAMLINED)**

***5412***

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be refractory to an enuresis alarm.

**Authority required (STREAMLINED)**

***5226***

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

**desmopressin 120 microgram sublingual wafer, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9398P NP | 1 | 5 | .. | 66.73 | 38.80 | Minirin Melt [FP] |

**desmopressin 240 microgram sublingual wafer, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8975J NP | 1 | 5 | .. | 105.68 | 38.80 | Minirin Melt [FP] |

## HYPOTHALAMIC HORMONES

*Gonadotropin-releasing hormones*

### ▪ NAFARELIN

**Restricted benefit**

Endometriosis

Treatment Phase: Initial treatment, for up to 6 months

**Clinical criteria:**

- The condition must be visually proven.

**Restricted benefit**

Endometriosis

Treatment Phase: Subsequent treatment, for up to 6 months

**Clinical criteria:**

- The condition must be visually proven, **AND**
- The treatment must not be within 2 years of the end of the previous course of treatment with this drug, **AND**
- Patient must have had a recent bone density assessment.

The date of the bone density assessment must be recorded in the patient's medical records.

**nafarelin 200 microgram/actuation nasal spray, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2962X | ‡1 | 5 | .. | 125.06 | 38.80 | Synarel [PF] |

# ▪ CORTICOSTEROIDS FOR SYSTEMIC USE

## CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN

*Mineralocorticoids*

### ▪ FLUDROCORTISONE ACETATE

**Note Continuing Therapy Only:**

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

**fludrocortisone acetate 100 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1433K NP | 2 | 1 | .. | *44.89 | 38.80 | Florinef [QA] |

*Glucocorticoids*

### ▪ BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE

**Restricted benefit**

Local intra-articular or peri-articular infiltration

**Restricted benefit**

Keloid

**Restricted benefit**

Lichen planus hypertrophic

**betamethasone (as sodium phosphate) 2.96 mg/mL + betamethasone (as acetate) 2.71 mg/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5034Y DP | 1 | .. | .. | 27.25 | 28.46 | Celestone Chronodose [MK] |

## ▪ BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE

**Note Shared Care Model**:

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

**Restricted benefit**

Alopecia areata

**Restricted benefit**

Local intra-articular or peri-articular infiltration

**Restricted benefit**

Granulomata

**Clinical criteria:**

- The condition must be dermal.

**Restricted benefit**

Keloid

**Restricted benefit**

Lichen planus hypertrophic

**Restricted benefit**

Lichen simplex chronicus

**Restricted benefit**

Chronic discoid lupus erythematosus

**Restricted benefit**

Necrobiosis lipoidica

**Restricted benefit**

Uveitis

**betamethasone (as sodium phosphate) 2.96 mg/mL + betamethasone (as acetate) 2.71 mg/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2694T NP | 1 | .. | .. | 27.25 | 28.46 | Celestone Chronodose [MK] |

## ▪ CORTISONE

**Note Continuing Therapy Only:**

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

**cortisone acetate 25 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1247P NP | 1 | 4 | .. | 23.55 | 24.76 | Cortate [AS] |

**cortisone acetate 5 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1246N NP | 1 | 4 | .. | 18.42 | 19.63 | Cortate [AS] |

## ▪ DEXAMETHASONE

**Note Shared Care Model**:

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

**DEXAMETHASONE Tablet 500 micrograms, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1292B NP | 1 | 4 | .. | 13.19 | 14.40 | Dexmethsone [AS] |

**DEXAMETHASONE Tablet 4 mg, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2507Y NP | 1 | 4 | .. | 16.29 | 17.50 | Dexmethsone [AS] |

## ▪ DEXAMETHASONE SODIUM PHOSPHATE

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

**DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 8 mg dexamethasone phosphate in 2 mL, 5**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1291Y NP | 1 | 1 | .. | 20.67 | 21.88 | [a] Dexamethasone Mylan [AF] | [a] Hospira Pty Limited [PF] |

**DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 4 mg dexamethasone phosphate in 1 mL, 5**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2509C NP | 1 | .. | .. | 16.36 | 17.57 | [a] Dexamethasone Mylan [AF] | [a] Hospira Pty Limited [PF] |

## ▪ HYDROCORTISONE

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

**hydrocortisone 4 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1499X NP | 1 | 4 | .. | 25.55 | 26.76 | Hysone 4 [AF] |

**hydrocortisone 20 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1500Y NP | 1 | 4 | .. | 31.73 | 32.94 | Hysone 20 [AF] |

## ▪ HYDROCORTISONE SODIUM SUCCINATE

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1501B NP | 2 | .. | .. | *20.89 | 22.10 | Solu-Cortef [PF] |

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3096Y NP | 1 | .. | .. | 19.85 | 21.06 | Solu-Cortef [PF] |

## ▪ HYDROCORTISONE SODIUM SUCCINATE

**Restricted benefit**
For use in a hospital

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1510L NP | 6 | .. | .. | *40.51 | 38.80 | Solu-Cortef [PF] |

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5118J DP | 6 | .. | .. | *40.51 | 38.80 | Solu-Cortef [PF] |

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1511M NP | 6 | .. | .. | *63.67 | 38.80 | Solu-Cortef [PF] |

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5119K DP | 6 | .. | .. | *63.67 | 38.80 | Solu-Cortef [PF] |

## ▪ METHYLPREDNISOLONE

**methylprednisolone Powder for injection 1 g (as sodium succinate), 1**

| 5264C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 43.59 | 38.80 | [a] Methylpred [AL] | [a] Methylprednisolone Alphapharm [AF] |
| | | | | | | [a] Solu-Medrol [PF] | |

## ▪ METHYLPREDNISOLONE

**Restricted benefit**

Local intra-articular or peri-articular infiltration

**methylprednisolone acetate 40 mg/mL injection, 5 x 1 mL vials**

| 1928L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 22.47 | 23.68 | [a] Depo-Nisolone [FZ] |
| | | | [B]2.61 | 25.08 | 23.68 | [a] Depo-Medrol [PF] |

## ▪ METHYLPREDNISOLONE

**Note** Pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) and pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) with diluent are equivalent for the purposes of substitution.

**methylprednisolone Powder for injection 40 mg (as sodium succinate), 5**

| 5263B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 23.23 | 24.44 | [a] Methylpred [AL] |

**methylprednisolone 40 mg injection [5 vials] (&) inert substance diluent [5 x 1 mL vials], 1 pack**

| 2981X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 26.52 | 27.73 | [a] Solu-Medrol [PF] |

## ▪ METHYLPREDNISOLONE

**Restricted benefit**

Local intra-articular or peri-articular infiltration

**methylprednisolone acetate 40 mg/mL injection, 5 x 1 mL vials**

| 5148Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 22.47 | 23.68 | [a] Depo-Nisolone [FZ] |
| | | | [B]2.61 | 25.08 | 23.68 | [a] Depo-Medrol [PF] |

## ▪ PREDNISOLONE

**prednisolone 5 mg tablet, 60**

| 1917X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 4 | .. | 14.09 | 15.30 | Panafcortelone [AS] | Solone [IA] |

**prednisolone 1 mg tablet, 100**

| 3152X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 4 | .. | 13.65 | 14.86 | [a] Predsolone [LN] |
| | | | [B]1.00 | 14.65 | 14.86 | [a] Panafcortelone [AS] |

**prednisolone 25 mg tablet, 30**

| 1916W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 4 | .. | 15.37 | 16.58 | Panafcortelone [AS] | Solone [IA] |

## ▪ PREDNISOLONE SODIUM PHOSPHATE

**prednisolone (as sodium phosphate) 5 mg/mL oral liquid, 30 mL**

| 8285C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 18.29 | 19.50 | [a] PredMix [LN] |
| | | | [B]2.35 | 20.64 | 19.50 | [a] Redipred [AS] |

## ▪ PREDNISONE

**prednisone 5 mg tablet, 60**

| 1935W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 4 | .. | 14.00 | 15.21 | Panafcort [AS] | Sone [IA] |

**prednisone 25 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1936X NP | 1 | 4 | .. | 15.43 | 16.64 | Panafcort [AS] | Sone [IA] |

**prednisone 1 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1934T NP | 1 | 4 | .. | 13.60 | 14.81 | [a] Predsone [LN] |
| | | | [B]1.00 | 14.60 | 14.81 | [a] Panafcort [AS] |

## ▪ TRIAMCINOLONE

**Restricted benefit**

Local intra-articular or peri-articular infiltration

**Restricted benefit**

Keloid

**Restricted benefit**

Lichen planus hypertrophic

**triamcinolone acetonide 10 mg/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5233K DP | 1 | .. | .. | 27.25 | 28.46 | Kenacort-A10 [QA] |

## ▪ TRIAMCINOLONE

**Note Shared Care Model**:

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

**Restricted benefit**

Alopecia areata

**Restricted benefit**

Local intra-articular or peri-articular infiltration

**Restricted benefit**

Granulomata

**Clinical criteria:**

- The condition must be dermal.

**Restricted benefit**

Keloid

**Restricted benefit**

Lichen planus hypertrophic

**Restricted benefit**

Lichen simplex chronicus

**Restricted benefit**

Chronic discoid lupus erythematosus

**Restricted benefit**

Necrobiosis lipoidica

**Restricted benefit**

Psoriasis

**triamcinolone acetonide 10 mg/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2990J NP | 1 | .. | .. | 27.25 | 28.46 | Kenacort-A10 [QA] |

# ▪ THYROID THERAPY

## THYROID PREPARATIONS

*Thyroid hormones*

## ▪ LIOTHYRONINE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6382***

Thyroid cancer

**Authority required (STREAMLINED)**

***6410***

Hypothyroidism

**Clinical criteria:**

- The treatment must be for replacement therapy, **AND**
- Patient must have documented intolerance to thyroxine sodium; OR
- Patient must have documented resistance to thyroxine sodium.

**Authority required (STREAMLINED)**

***6475***

Hypothyroidism

**Clinical criteria:**

- The condition must be severe hypothyroidism, **AND**
- The treatment must be for initiation of therapy only.

**liothyronine sodium 20 microgram tablet, 100**

| 2318B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 77.69 | 38.80 | Tertroxin [QA] |

## ▪ THYROXINE

**Note Continuing Therapy Only:**

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

**thyroxine sodium 75 microgram tablet, 200**

| 9287T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 26.39 | 27.60 | [a] Eutroxsig [FM] |
| | | | [B]1.98 | 28.37 | 27.60 | [a] Oroxine [QA] |

**thyroxine sodium 100 microgram tablet, 200**

| 2175L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 26.36 | 27.57 | [a] Eutroxsig [FM] |
| | | | [B]1.92 | 28.28 | 27.57 | [a] Oroxine [QA] |

**thyroxine sodium 50 microgram tablet, 200**

| 2174K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 25.83 | 27.04 | [a] Eutroxsig [FM] |
| | | | [B]1.91 | 27.74 | 27.04 | [a] Oroxine [QA] |

**thyroxine sodium 200 microgram tablet, 200**

| 2173J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 28.99 | 30.20 | [a] Eutroxsig [FM] |
| | | | [B]1.93 | 30.92 | 30.20 | [a] Oroxine [QA] |

## ANTITHYROID PREPARATIONS

### *Thiouracils*

## ▪ PROPYLTHIOURACIL

**Note Continuing Therapy Only:**

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

**propylthiouracil 50 mg tablet, 100**

| 1955X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | .. | *47.89 | 38.80 | PTU [PL] |

### *Sulfur-containing imidazole derivatives*

## ▪ CARBIMAZOLE

**Note Continuing Therapy Only:**

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

**carbimazole 5 mg tablet, 100**

| 1153Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | .. | *31.41 | 32.62 | Carbimazol ARISTO [PQ] | Neo-Mercazole [GH] |

# PANCREATIC HORMONES

## GLYCOGENOLYTIC HORMONES

*Glycogenolytic hormones*

### GLUCAGON HYDROCHLORIDE

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1449G NP | 1 | 1 | .. | 50.97 | 38.80 | GlucaGen Hypokit [NO] |

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5105Q DP | 1 | .. | .. | 50.97 | 38.80 | GlucaGen Hypokit [NO] |

# CALCIUM HOMEOSTASIS

## PARATHYROID HORMONES AND ANALOGUES

*Parathyroid hormones and analogues*

### TERIPARATIDE

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

**Authority required**

Severe established osteoporosis

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

**Clinical criteria:**

- Patient must be at very high risk of fracture, **AND**
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less, **AND**
- Patient must have had 2 or more fractures due to minimal trauma, **AND**
- Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, **AND**
- The treatment must be the sole PBS-subsidised agent, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy**.** Details must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.

**Note** Details of accepted toxicities including severity can be found on the Department of Human Services website at www.humanservices.gov.au.

**Authority required**

Severe established osteoporosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

**Note** Up to a maximum of 18 pens will be reimbursed through the PBS.

**teriparatide 20 microgram injection, 2.4 mL cartridge**

| 9411H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 411.80 | 38.80 | Forteo [LY] |

## ANTI-PARATHYROID AGENTS

*Calcitonin preparations*

### ▪ SALCATONIN

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

**Restricted benefit**
Symptomatic Paget disease of bone
**Restricted benefit**
Hypercalcaemia
**Clinical criteria:**
- The treatment must be initiated in a hospital.

**salcatonin 100 units/mL injection, 5 x 1 mL ampoules**

| 2997R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 5 | .. | *144.67 | 38.80 | Miacalcic 100 [NV] |

# ▪ ANTIINFECTIVES FOR SYSTEMIC USE

# ▪ ANTIBACTERIALS FOR SYSTEMIC USE

## TETRACYCLINES

*Tetracyclines*

### ▪ DOXYCYCLINE

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

**doxycycline 100 mg tablet, 7**

| 2709N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 12.55 | 13.76 | [a] Doxsig [RW]<br>[a] Doxylin 100 [AF] | [a] Doxycycline AN [EA] |

**doxycycline 100 mg tablet, 7**

| 3321T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 12.55 | 13.76 | [a] Doxsig [RW]<br>[a] Doxylin 100 [AF] | [a] Doxycycline AN [EA] |

**doxycycline 100 mg tablet, 7**

| 5082L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 12.55 | 13.76 | [a] APO-Doxycycline [TX]<br>[a] Doxycycline Sandoz [HX]<br>[a] Terry White Chemists Doxycycline [TW] | [a] Chem mart Doxycycline [CH]<br>[a] GenRx Doxycycline [GX] |

**doxycycline 100 mg tablet, 7**

| 9105F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 12.55 | 13.76 | [a] APO-Doxycycline [TX]<br>[a] Doxycycline Sandoz [HX]<br>[a] Terry White Chemists Doxycycline [TW] | [a] Chem mart Doxycycline [CH]<br>[a] GenRx Doxycycline [GX] |

**doxycycline 100 mg modified release capsule, 7**

| 2708M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | [B]1.54 | 14.09 | 13.76 | [a] Mayne Pharma Doxycycline [YT] |
| | | | [B]2.96 | 15.51 | 13.76 | [a] Doryx [YN] |

**doxycycline 100 mg modified release capsule, 7**

| 3322W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | [B]1.54 | 14.09 | 13.76 | [a] Mayne Pharma Doxycycline [YT] |
| | | | [B]2.96 | 15.51 | 13.76 | [a] Doryx [YN] |

## ▪ DOXYCYCLINE

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

**Restricted benefit**

Urethritis

**doxycycline 100 mg tablet, 21**

| 10176N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 15.48 | 16.69 | [a] Doxycycline AN [EA] | [a] Doxylin 100 [AF] |

**doxycycline 100 mg tablet, 21**

| 1800R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 15.48 | 16.69 | [a] APO-Doxycycline [TX] | [a] GenRx Doxycycline [GX] |

**doxycycline 100 mg modified release capsule, 21**

| 2715X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | [B]3.21 | 18.69 | 16.69 | [a] Mayne Pharma Doxycycline [YT] |
| | | | [B]9.00 | 24.48 | 16.69 | [a] Doryx [YN] |

**doxycycline 100 mg tablet, 7**

| 2714W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 3 | .. | .. | *15.46 | 16.67 | [a] Doxsig [RW]<br>[a] Doxylin 100 [AF] | [a] Doxycycline AN [EA] |

**doxycycline 100 mg tablet, 7**

| 9108J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 3 | .. | .. | *15.46 | 16.67 | [a] Chem mart Doxycycline [CH]<br>[a] Terry White Chemists Doxycycline [TW] | [a] Doxycycline Sandoz [HX] |

## ▪ DOXYCYCLINE

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

**Restricted benefit**

Severe acne

**doxycycline 100 mg tablet, 7**

| 10779H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 4 | 5 | .. | *16.95 | 18.16 | [a] Doxsig [RW]<br>[a] Doxylin 100 [AF] | [a] Doxycycline AN [EA] |

**doxycycline 100 mg tablet, 7**

| 10781K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 4 | 5 | .. | *16.95 | 18.16 | [a] APO-Doxycycline [TX]<br>[a] Doxycycline Sandoz [HX]<br>[a] Terry White Chemists Doxycycline [TW] | [a] Chem mart Doxycycline [CH]<br>[a] GenRx Doxycycline [GX] |

**doxycycline 100 mg modified release capsule, 7**

| 10777F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | 5 | [B]6.16 | *23.11 | 18.16 | [a] Mayne Pharma Doxycycline [YT] |
| | | | [B]11.84 | *28.79 | 18.16 | [a] Doryx [YN] |

## ▪ DOXYCYCLINE

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

**Restricted benefit**

Pelvic inflammatory disease

**doxycycline 100 mg tablet, 7**

| 2702F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | .. | .. | *16.95 | 18.16 | [a] Doxsig [RW]<br>[a] Doxylin 100 [AF] | [a] Doxycycline AN [EA] |

**doxycycline 100 mg tablet, 7**

| 9107H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | .. | .. | *16.95 | 18.16 | [a] APO-Doxycycline [TX]<br>[a] Doxycycline Sandoz [HX]<br>[a] Terry White Chemists Doxycycline [TW] | [a] Chem mart Doxycycline [CH]<br>[a] GenRx Doxycycline [GX] |

**doxycycline 100 mg modified release capsule, 7**

| 2703G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | .. | [B]6.16 | *23.11 | 18.16 | [a] Mayne Pharma Doxycycline [YT] |
| | | | [B]11.84 | *28.79 | 18.16 | [a] Doryx [YN] |

## ▪ DOXYCYCLINE

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 50 mg (as hydrochloride), doxycycline tablet 50 mg (as monohydrate) and doxycycline capsule: modified release 50 mg (as hydrochloride) are equivalent for the purposes of substitution.

**Restricted benefit**

Bronchiectasis

**Population criteria:**

- Patient must be aged 8 years or older.

**Restricted benefit**

Chronic bronchitis

**Population criteria:**

- Patient must be aged 8 years or older.

**Restricted benefit**

Severe acne

**doxycycline 50 mg tablet, 25**

| 2711Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 13.42 | 14.63 | [a] Doxycycline AN [EA] | [a] Doxylin 50 [AF] |

**doxycycline 50 mg tablet, 25**

| 9106G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 13.42 | 14.63 | [a] APO-Doxycycline [TX]<br>[a] Doxycycline Sandoz [HX]<br>[a] GenRx Doxycycline [GX] | [a] Chem mart Doxycycline [CH]<br>[a] Frakas [RW]<br>[a] Terry White Chemists Doxycycline [TW] |

**doxycycline 50 mg modified release capsule, 25**

| 2707L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | [B]2.59 | 16.01 | 14.63 | [a] Mayne Pharma Doxycycline [YT] |
| | | | [B]5.01 | 18.43 | 14.63 | [a] Doryx [YN] |

## ▪ MINOCYCLINE

**Caution** There are concerns about the incidence of benign intracranial hypertension associated with this drug.

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

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

**Restricted benefit**

Severe acne

**Clinical criteria:**

- The condition must not be responding to other tetracyclines.

**minocycline 50 mg tablet, 60**

| 1616C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 18.59 | 19.80 | [a] Akamin 50 [AF] |
| | | | [B]1.65 | 20.24 | 19.80 | [a] Minomycin-50 [QA] |

## BETA-LACTAM ANTIBACTERIALS, PENICILLINS

*Penicillins with extended spectrum*

## ▪ AMOXYCILLIN

### amoxycillin 100 mg/mL powder for oral liquid, 20 mL

| 1888J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | [S]0.53 | #18.03 | 19.07 | Amoxil [AS] |

### amoxycillin 100 mg/mL powder for oral liquid, 20 mL

| 3310F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | ‡1 | .. | [S]0.53 | #18.03 | 19.07 | Amoxil [AS] |

### amoxycillin 125 mg/5 mL powder for oral liquid, 100 mL

| 1886G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | .. | #15.20 | 16.77 | [a] Alphamox 125 [AF]<br>[a] APO-Amoxycillin [TX] | [a] Amoxycillin Sandoz [SZ]<br>[a] Ranmoxy [RA] |
| | | | [B]3.46 | #18.66 | 16.77 | [a] Amoxil [AS] | |

### amoxycillin 125 mg/5 mL powder for oral liquid, 100 mL

| 3302T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | ‡1 | .. | .. | #15.20 | 16.77 | [a] Alphamox 125 [AF]<br>[a] APO-Amoxycillin [TX] | [a] Amoxycillin Sandoz [SZ]<br>[a] Ranmoxy [RA] |
| | | | [B]3.46 | #18.66 | 16.77 | [a] Amoxil [AS] | |

### amoxycillin 250 mg/5 mL powder for oral liquid, 100 mL

| 1887H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | .. | #15.53 | 17.10 | [a] Alphamox 250 [AF]<br>[a] APO-Amoxycillin [TX]<br>[a] Ranmoxy [RA] | [a] Amoxycillin Sandoz [SZ]<br>[a] Cilamox [QA] |
| | | | [B]3.56 | #19.09 | 17.10 | [a] Amoxil Forte [AS] | |

### amoxycillin 250 mg/5 mL powder for oral liquid, 100 mL

| 3393N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | ‡1 | .. | .. | #15.53 | 17.10 | [a] Alphamox 250 [AF]<br>[a] APO-Amoxycillin [TX]<br>[a] Ranmoxy [RA] | [a] Amoxycillin Sandoz [SZ]<br>[a] Cilamox [QA] |
| | | | [B]3.56 | #19.09 | 17.10 | [a] Amoxil Forte [AS] | |

### amoxycillin 500 mg capsule, 20

| 1889K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | .. | 12.81 | 14.02 | [a] Alphamox 500 [AF]<br>[a] Amoxycillin generichealth 500 [GQ]<br>[a] Amoxycillin Sandoz [SZ]<br>[a] Chem mart Amoxycillin [CH]<br>[a] Terry White Chemists Amoxycillin [TW] | [a] Amoxycillin AN [EA]<br>[a] Amoxycillin Ranbaxy [RA]<br>[a] APO-Amoxycillin [TX]<br>[a] Cilamox [QA]<br>[a] Yomax 500 [DO] |
| | | | [B]3.76 | 16.57 | 14.02 | [a] Amoxil [AS] | |

### amoxycillin 500 mg capsule, 20

| 3300Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 12.81 | 14.02 | [a] Alphamox 500 [AF]<br>[a] Amoxycillin generichealth 500 [GQ]<br>[a] Amoxycillin Sandoz [SZ]<br>[a] Chem mart Amoxycillin [CH]<br>[a] Terry White Chemists Amoxycillin [TW] | [a] Amoxycillin AN [EA]<br>[a] Amoxycillin Ranbaxy [RA]<br>[a] APO-Amoxycillin [TX]<br>[a] Cilamox [QA]<br>[a] Yomax 500 [DO] |
| | | | [B]3.76 | 16.57 | 14.02 | [a] Amoxil [AS] | |

### amoxycillin 500 mg/5 mL powder for oral liquid, 100 mL

| 5225B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | ‡1 | .. | .. | #15.63 | 17.20 | Maxamox [SZ] |

### amoxycillin 500 mg/5 mL powder for oral liquid, 100 mL

| 8705E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | .. | #15.63 | 17.20 | Maxamox [SZ] |

**amoxycillin 250 mg capsule, 20**

| 1884E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | .. | 12.49 | 13.70 | [a] Alphamox 250 [AF]<br>[a] Amoxycillin Ranbaxy [RA]<br>[a] APO-Amoxycillin [TX]<br>[a] Cilamox [QA]<br>[a] Yomax 250 [DO] | [a] Amoxycillin AN [EA]<br>[a] Amoxycillin Sandoz [SZ]<br>[a] Chem mart Amoxycillin [CH]<br>[a] Terry White Chemists Amoxycillin [TW] |
| | | | [B]3.49 | 15.98 | 13.70 | [a] Amoxil [AS] | |

**amoxycillin 250 mg capsule, 20**

| 3301R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 12.49 | 13.70 | [a] Alphamox 250 [AF]<br>[a] Amoxycillin Ranbaxy [RA]<br>[a] APO-Amoxycillin [TX]<br>[a] Cilamox [QA]<br>[a] Yomax 250 [DO] | [a] Amoxycillin AN [EA]<br>[a] Amoxycillin Sandoz [SZ]<br>[a] Chem mart Amoxycillin [CH]<br>[a] Terry White Chemists Amoxycillin [TW] |
| | | | [B]3.49 | 15.98 | 13.70 | [a] Amoxil [AS] | |

## ▪ AMOXYCILLIN

**Restricted benefit**

Chronic bronchitis

**Clinical criteria:**

- Patient must have acute exacerbations of the condition.

**amoxycillin 1 g tablet, 14**

| 8581P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 12.67 | 13.88 | [a] Amoxycillin Sandoz [BG] |
| | | | [B]1.08 | 13.75 | 13.88 | [a] Maxamox [SZ] |

## ▪ AMOXYCILLIN

**Authority required**

Infection suspected or proven to be due to a susceptible organism

**Clinical criteria:**

- The treatment must be for patients who require a liquid formulation and in whom the syrup formulations are unsuitable.

**amoxycillin 100 mg/mL powder for oral liquid, 20 mL**

| 9714G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | .. | #18.03 | 19.60 | Amoxil [AS] |

## ▪ AMPICILLIN

**ampicillin 500 mg injection, 5 vials**

| 2390T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 16.05 | 17.26 | Austrapen [AL] |

**ampicillin 500 mg injection, 5 vials**

| 3313J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 16.05 | 17.26 | Austrapen [AL] |

**ampicillin 1 g injection, 5 vials**

| 2977Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 17.23 | 18.44 | [a] Ampicyn [AF] | [a] Austrapen [AL] |

**ampicillin 1 g injection, 5 vials**

| 3314K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 17.23 | 18.44 | [a] Ampicyn [AF] | [a] Austrapen [AL] |

*Beta-lactamase sensitive penicillins*

## ▪ BENZATHINE BENZYLPENICILLIN

**BENZATHINE BENZYLPENICILLIN Injection 900 mg in 2.3 mL single use pre-filled syringe, 10**

| 2267H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 309.22 | 38.80 | Bicillin L-A [PF] |

**BENZATHINE BENZYLPENICILLIN Injection 900 mg in 2.3 mL single use pre-filled syringe, 10**

| 5027N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 309.22 | 38.80 | Bicillin L-A [PF] |

## ▪ BENZYLPENICILLIN

**benzylpenicillin 3 g injection, 1 vial**

| 2647H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 10 | .. | .. | *97.95 | 38.80 | BenPen [CS] |

**benzylpenicillin 3 g injection, 1 vial**

| 3399X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 10 | .. | .. | *97.95 | 38.80 | BenPen [CS] |

**benzylpenicillin 600 mg injection, 1 vial**

| 1775K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 10 | 1 | .. | *61.35 | 38.80 | BenPen [CS] |

**benzylpenicillin 600 mg injection, 1 vial**

| 3398W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 10 | .. | .. | *61.35 | 38.80 | BenPen [CS] |

## ▪ PHENOXYMETHYLPENICILLIN

**phenoxymethylpenicillin 250 mg capsule, 50**

| 1789E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 15.21 | 16.42 | Cilicaine VK [FM] | LPV [IA] |

**phenoxymethylpenicillin 250 mg capsule, 50**

| 3363B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 15.21 | 16.42 | Cilicaine VK [FM] | LPV [IA] |

**phenoxymethylpenicillin 125 mg/5 mL powder for oral liquid, 100 mL**

| 5024K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 2 | .. | .. | *#20.56 | 22.13 | Phenoxymethylpenicillin-AFT [AE] |

**phenoxymethylpenicillin 125 mg/5 mL powder for oral liquid, 100 mL**

| 8976K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 1 | .. | *#20.56 | 22.13 | Phenoxymethylpenicillin-AFT [AE] |

**phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL**

| 5029Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 2 | .. | .. | *#22.80 | 24.37 | Phenoxymethylpenicillin-AFT [AE] |

**phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL**

| 8977L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 1 | .. | *#22.80 | 24.37 | Phenoxymethylpenicillin-AFT [AE] |

**phenoxymethylpenicillin 500 mg tablet, 25**

| 3028J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *17.39 | 18.60 | Aspecillin VK [QA] |

**phenoxymethylpenicillin 500 mg tablet, 25**

| 3361X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 2 | .. | .. | *17.39 | 18.60 | Aspecillin VK [QA] |

**phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL**

| 5012T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 2 | .. | .. | *24.29 | 25.50 | Cilicaine V [FM] |

**phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9143F NP | 2 | 1 | .. | *24.29 | 25.50 | Cilicaine V [FM] |

**phenoxymethylpenicillin 250 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1787C NP | 2 | .. | .. | *15.35 | 16.56 | Aspecillin VK [QA] |

**phenoxymethylpenicillin 250 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3360W DP | 2 | .. | .. | *15.35 | 16.56 | Aspecillin VK [QA] |

**phenoxymethylpenicillin 500 mg capsule, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2965C NP | 1 | .. | .. | 17.22 | 18.43 | Cilicaine VK [FM] | LPV [IA] |

**phenoxymethylpenicillin 500 mg capsule, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3364C DP | 1 | .. | .. | 17.22 | 18.43 | Cilicaine VK [FM] | LPV [IA] |

## ▪ PHENOXYMETHYLPENICILLIN

**Restricted benefit**

Recurrent streptococcal infections (including rheumatic fever)

**Clinical criteria:**

- The treatment must be for prophylaxis.

**phenoxymethylpenicillin 250 mg capsule, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1705R NP | 1 | 5 | .. | 15.21 | 16.42 | Cilicaine VK [FM] | LPV [IA] |

**phenoxymethylpenicillin 250 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1703P NP | 2 | 5 | .. | *15.35 | 16.56 | Aspecillin VK [QA] |

## ▪ PROCAINE PENICILLIN

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1794K NP | 1 | .. | .. | 85.18 | 38.80 | Cilicaine [QA] |

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3371K DP | 1 | .. | .. | 85.18 | 38.80 | Cilicaine [QA] |

### *Beta-lactamase resistant penicillins*

## ▪ DICLOXACILLIN

**Restricted benefit**

Serious staphylococcal infection

**dicloxacillin 250 mg capsule, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5096F DP | 1 | .. | .. | 16.60 | 17.81 | Distaph 250 [AF] |

**dicloxacillin 500 mg capsule, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5097G DP | 1 | .. | .. | 20.73 | 21.94 | Distaph 500 [AF] |

## ▪ DICLOXACILLIN

**Restricted benefit**

Serious staphylococcal infection

**dicloxacillin 250 mg capsule, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8121K NP MW | 1 | .. | .. | 16.60 | 17.81 | Distaph 250 [AF] |

**dicloxacillin 500 mg capsule, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8122L NP MW | 1 | .. | .. | 20.73 | 21.94 | Distaph 500 [AF] |

## ▪ DICLOXACILLIN

**Authority required (STREAMLINED)**

***6188***

Osteomyelitis

**dicloxacillin 500 mg capsule, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10790X | 2 | 1 | .. | *30.37 | 31.58 | Distaph 500 [AF] |

## ▪ FLUCLOXACILLIN

**Caution** Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Note** Pharmaceutical benefits that have the form flucloxacillin 1 g injection in a pack size of 5 can be substituted for a pack size of 10 in the case of a shortage.

**flucloxacillin 1 g injection, 5 vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1525G NP | 1 | 1 | .. | 16.41 | 17.62 | [a] Flucil [AS] |

**flucloxacillin 1 g injection, 5 vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5095E DP | 1 | .. | .. | 16.41 | 17.62 | [a] Flucil [AS] |

**flucloxacillin 1 g injection, 10 vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10605E NP | 0.5 | 1 | .. | *19.46 | 20.67 | [a] Hospira Pty Limited [PF] |

**flucloxacillin 1 g injection, 10 vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10609J DP | 0.5 | .. | .. | *19.46 | 20.67 | [a] Hospira Pty Limited [PF] |

## ▪ FLUCLOXACILLIN

**Caution** Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Restricted benefit**

Serious staphylococcal infection

**flucloxacillin 500 mg capsule, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1527J NP MW | 1 | .. | .. | 19.78 | 20.99 | [a] APO-Flucloxacillin [TX]<br>[a] Staphylex 500 [AF] | [a] Flopen [AS] |

**flucloxacillin 250 mg capsule, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1526H NP MW | 1 | .. | .. | 15.24 | 16.45 | [a] APO-Flucloxacillin [TX]<br>[a] Staphylex 250 [AF] | [a] Flopen [AS] |

## ▪ FLUCLOXACILLIN

**Caution** Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Restricted benefit**

Serious staphylococcal infection

**flucloxacillin 500 mg capsule, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5091Y DP | 1 | .. | .. | 19.78 | 20.99 | [a] APO-Flucloxacillin [TX]<br>[a] Staphylex 500 [AF] | [a] Flopen [AS] |

**flucloxacillin 250 mg/5 mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5258R DP | ‡1 | .. | .. | #23.02 | 24.59 | Flucil [LN] |

**flucloxacillin 125 mg/5 mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5257Q DP | ‡1 | .. | .. | #19.95 | 21.52 | Flucil [LN] |

**flucloxacillin 250 mg capsule, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5090X DP | 1 | .. | .. | 15.24 | 16.45 | [a] APO-Flucloxacillin [TX]<br>[a] Staphylex 250 [AF] | [a] Flopen [AS] |

## ▪ FLUCLOXACILLIN

**Caution** Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Restricted benefit**

Serious staphylococcal infection

**flucloxacillin 250 mg/5 mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9150N NP | ‡1 | 1 | .. | #23.02 | 24.59 | Flucil [LN] |

**flucloxacillin 125 mg/5 mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9149M NP | ‡1 | 1 | .. | #19.95 | 21.52 | Flucil [LN] |

## ▪ FLUCLOXACILLIN

**Caution** Severe cholestatic jaundice has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Authority required (STREAMLINED)**

***6169***

Osteomyelitis

**flucloxacillin 500 mg capsule, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10788T | 2 | 1 | .. | *28.47 | 29.68 | [a] APO-Flucloxacillin [TX]<br>[a] Staphylex 500 [AF] | [a] Flopen [AS] |

*Combinations of penicillins, incl. beta-lactamase inhibitors*

## ▪ AMOXYCILLIN + CLAVULANIC ACID

**Caution** Hepatotoxicity has been reported with this drug.

**Restricted benefit**

Infection where resistance to amoxycillin is suspected

**Restricted benefit**

Infections where resistance to amoxycillin is proven

**amoxycillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL powder for oral liquid, 60 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8319W NP | ‡1 | 1 | .. | #15.86 | 17.43 | [a] APO-Amoxycillin and Clavulanic Acid 400/57 [TX] | [a] Curam Duo [SZ] |
| | | | [B]4.84 | #20.70 | 17.43 | [a] Augmentin Duo 400 [AS] | |

**amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8254K NP | 1 | 1 | .. | 13.86 | 15.07 | [a] AlphaClav Duo Forte [AF]<br>[a] AmoxyClav generichealth 875/125 [HQ]<br>[a] APO-Amoxycillin and Clavulanic Acid [TX]<br>[a] Clavam 875 mg/125 mg [CR]<br>[a] Moxiclav Duo Forte 875/125 [QA] | [a] Amoxyclav AN 875/125 [EA]<br>[a] AmoxyClav GH 875/125 [GQ]<br>[a] Chem mart Amoxycillin and Clavulanic Acid [CH]<br>[a] Curam Duo Forte 875/125 [SZ]<br>[a] Terry White Chemists Amoxycillin and Clavulanic Acid [TW] |
| | | | [B]6.24 | 20.10 | 15.07 | [a] Augmentin Duo forte [AS] | |

**amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1891M NP MW | 1 | 1 | .. | 13.56 | 14.77 | [a] AlphaClav Duo [AF]<br>[a] APO-Amoxycillin/ Clavulanic Acid 500/125 [TX]<br>[a] Moxiclav Duo 500/125 [QA] | [a] Amoxyclav AN 500/125 [EA]<br>[a] Curam Duo 500/125 [SZ] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | [B]4.87 | 18.43 | 14.77 | [a] Augmentin Duo [AS] | |

**amoxycillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL**

| 1892N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | .. | #15.54 | 17.11 | [a] APO-Amoxycillin and Clavulanic Acid 125/31.25 [TX] | [a] Curam [SZ] |
| | | | [B]3.45 | #18.99 | 17.11 | [a] Augmentin [AS] | |

## ▪ AMOXYCILLIN + CLAVULANIC ACID

**Caution** Hepatotoxicity has been reported with this drug.

**Restricted benefit**

Infection where resistance to amoxycillin is suspected

**Restricted benefit**

Infections where resistance to amoxycillin is proven

**amoxycillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL powder for oral liquid, 60 mL**

| 5011R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | ‡1 | .. | .. | #15.86 | 17.43 | [a] APO-Amoxycillin and Clavulanic Acid 400/57 [TX] | [a] Curam Duo [SZ] |
| | | | [B]4.84 | #20.70 | 17.43 | [a] Augmentin Duo 400 [AS] | |

**amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10**

| 5006L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 13.86 | 15.07 | [a] AlphaClav Duo Forte [AF] | [a] Amoxyclav AN 875/125 [EA] |
| | | | | | | [a] AmoxyClav generichealth 875/125 [HQ] | [a] AmoxyClav GH 875/125 [GQ] |
| | | | | | | [a] APO-Amoxycillin and Clavulanic Acid [TX] | [a] Chem mart Amoxycillin and Clavulanic Acid [CH] |
| | | | | | | [a] Clavam 875 mg/125 mg [CR] | [a] Curam Duo Forte 875/125 [SZ] |
| | | | | | | [a] Moxiclav Duo Forte 875/125 [QA] | [a] Terry White Chemists Amoxycillin and Clavulanic Acid [TW] |
| | | | [B]6.24 | 20.10 | 15.07 | [a] Augmentin Duo forte [AS] | |

**amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10**

| 5008N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 13.56 | 14.77 | [a] AlphaClav Duo [AF] | [a] Amoxyclav AN 500/125 [EA] |
| | | | | | | [a] APO-Amoxycillin/ Clavulanic Acid 500/125 [TX] | [a] Curam Duo 500/125 [SZ] |
| | | | | | | [a] Moxiclav Duo 500/125 [QA] | |
| | | | [B]4.87 | 18.43 | 14.77 | [a] Augmentin Duo [AS] | |

**amoxycillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL**

| 5009P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | ‡1 | .. | .. | #15.54 | 17.11 | [a] APO-Amoxycillin and Clavulanic Acid 125/31.25 [TX] | [a] Curam [SZ] |
| | | | [B]3.45 | #18.99 | 17.11 | [a] Augmentin [AS] | |

## ▪ TICARCILLIN + CLAVULANIC ACID

**Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**ticarcillin 3 g + clavulanic acid 100 mg injection, 3.1 g vial**

| 10125X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 10 | .. | .. | *146.65 | 38.80 | Timentin [AS] |

## ▪ TICARCILLIN + CLAVULANIC ACID

**Note Shared Care Model**:

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

**Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

**ticarcillin 3 g + clavulanic acid 100 mg injection, 3.1 g vial**

| 10113G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 10 | .. | .. | *146.65 | 38.80 | Timentin [AS] |

## OTHER BETA-LACTAM ANTIBACTERIALS

*First-generation cephalosporins*

### ▪ CEPHALEXIN

**cephalexin 250 mg capsule, 20**

| 3058Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | .. | 12.80 | 14.01 | [a] APO-Cephalexin [TX]<br>[a] Cephalex 250 [CR]<br>[a] Cilex [ED]<br>[a] Ibilex 250 [AF] | [a] Cefalexin Sandoz [SZ]<br>[a] Cephalexin AN [EA]<br>[a] Ialex [LN]<br>[a] Rancef [RA] |
| | | | [B]3.76 | 16.56 | 14.01 | [a] Keflex [AS] | |

**cephalexin 250 mg capsule, 20**

| 3317N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 12.80 | 14.01 | [a] APO-Cephalexin [TX]<br>[a] Cephalex 250 [CR]<br>[a] Cilex [ED]<br>[a] Ibilex 250 [AF] | [a] Cefalexin Sandoz [SZ]<br>[a] Cephalexin AN [EA]<br>[a] Ialex [LN]<br>[a] Rancef [RA] |
| | | | [B]3.76 | 16.56 | 14.01 | [a] Keflex [AS] | |

**cephalexin 500 mg capsule, 20**

| 3119E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | .. | 12.95 | 14.16 | [a] APO-Cephalexin [TX]<br>[a] Cephalex 500 [CR]<br>[a] Cephalexin generichealth [GQ]<br>[a] Ialex [LN]<br>[a] Rancef [RA] | [a] Cefalexin Sandoz [SZ]<br>[a] Cephalexin AN [EA]<br>[a] Cilex [ED]<br>[a] Ibilex 500 [AF] |
| | | | [B]5.47 | 18.42 | 14.16 | [a] Keflex [AS] | |

**cephalexin 500 mg capsule, 20**

| 3318P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 12.95 | 14.16 | [a] APO-Cephalexin [TX]<br>[a] Cephalex 500 [CR]<br>[a] Cephalexin generichealth [GQ]<br>[a] Ialex [LN]<br>[a] Rancef [RA] | [a] Cefalexin Sandoz [SZ]<br>[a] Cephalexin AN [EA]<br>[a] Cilex [ED]<br>[a] Ibilex 500 [AF] |
| | | | [B]5.47 | 18.42 | 14.16 | [a] Keflex [AS] | |

**cephalexin 125 mg/5 mL powder for oral liquid, 100 mL**

| 3094W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | .. | #15.78 | 17.35 | [a] APO-Cephalexin [TX]<br>[a] Chem mart Cephalexin [CH]<br>[a] Ibilex 125 [AF] | [a] Cefalexin Sandoz [SZ]<br>[a] Ialex [LN]<br>[a] Terry White Chemists Cephalexin [TW] |
| | | | [B]4.15 | #19.93 | 17.35 | [a] Keflex [AS] | |

**cephalexin 125 mg/5 mL powder for oral liquid, 100 mL**

| 3319Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | ‡1 | .. | .. | #15.78 | 17.35 | [a] APO-Cephalexin [TX]<br>[a] Chem mart Cephalexin [CH]<br>[a] Ibilex 125 [AF] | [a] Cefalexin Sandoz [SZ]<br>[a] Ialex [LN]<br>[a] Terry White Chemists Cephalexin [TW] |
| | | | [B]4.15 | #19.93 | 17.35 | [a] Keflex [AS] | |

**cephalexin 250 mg/5 mL powder for oral liquid, 100 mL**

| 3095X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | .. | #16.08 | 17.65 | [a] APO-Cephalexin [TX]<br>[a] Chem mart Cephalexin [CH]<br>[a] Ibilex 250 [AF] | [a] Cefalexin Sandoz [SZ]<br>[a] Ialex [LN]<br>[a] Terry White Chemists Cephalexin [TW] |
| | | | [B]5.69 | #21.77 | 17.65 | [a] Keflex [AS] | |

**cephalexin 250 mg/5 mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3320R DP | ‡1 | .. | .. | #16.08 | 17.65 | [a] APO-Cephalexin [TX]<br>[a] Chem mart Cephalexin [CH]<br>[a] Ibilex 250 [AF] | [a] Cefalexin Sandoz [SZ]<br>[a] Ialex [LN]<br>[a] Terry White Chemists Cephalexin [TW] |
| | | | [B]5.69 | #21.77 | 17.65 | [a] Keflex [AS] | |

## ▪ CEPHALEXIN

**Authority required (STREAMLINED)**

***6188***

Osteomyelitis

**cephalexin 500 mg capsule, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10778G | 2 | 1 | .. | *14.81 | 16.02 | [a] APO-Cephalexin [TX]<br>[a] Cephalex 500 [CR]<br>[a] Cephalexin generichealth [GQ]<br>[a] Ialex [LN]<br>[a] Rancef [RA] | [a] Cefalexin Sandoz [SZ]<br>[a] Cephalexin AN [EA]<br>[a] Cilex [ED]<br>[a] Ibilex 500 [AF] |
| | | | [B]10.94 | *25.75 | 16.02 | [a] Keflex [AS] | |

## ▪ CEPHALEXIN

**Authority required (STREAMLINED)**

***4243***

Prophylaxis of urinary tract infection

**cephalexin 250 mg capsule, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2655R | 2 | 2 | .. | *14.51 | 15.72 | [a] APO-Cephalexin [TX]<br>[a] Cephalex 250 [CR]<br>[a] Cilex [ED]<br>[a] Ibilex 250 [AF] | [a] Cefalexin Sandoz [SZ]<br>[a] Cephalexin AN [EA]<br>[a] Ialex [LN]<br>[a] Rancef [RA] |
| | | | [B]7.52 | *22.03 | 15.72 | [a] Keflex [AS] | |

## ▪ CEPHALOTHIN

**cephalothin 1 g injection, 10 vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2964B NP | 1 | 1 | .. | 25.56 | 26.77 | Hospira Pty Limited [PF] |

**cephalothin 1 g injection, 10 vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3376Q DP | 1 | .. | .. | 25.56 | 26.77 | Hospira Pty Limited [PF] |

## ▪ CEPHAZOLIN

**Restricted benefit**

Cellulitis

**cephazolin 500 mg injection, 5 vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5477G NP | 2 | .. | .. | *17.39 | 18.60 | Cefazolin-AFT [AE] |

**cephazolin 2 g injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5479J NP | 10 | .. | .. | *38.85 | 38.80 | Cephazolin Alphapharm [AF] |

## ▪ CEPHAZOLIN

**Note** For item codes 5478H and 1799Q, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

**Restricted benefit**

Cellulitis

**cephazolin 1 g injection, 5 vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1799Q NP | 2 | .. | .. | *20.87 | 22.08 | [a] Cefazolin-AFT [AE] | [a] Hospira Cefazolin Sodium [PF] |

**cephazolin 1 g injection, 10 vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5478H NP | 1 | .. | .. | 20.87 | 22.08 | [a] Cefazolin Sandoz [SZ] |

## ▪ CEPHAZOLIN

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

**Restricted benefit**
Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent
**Restricted benefit**
Septicaemia, suspected
**Restricted benefit**
Septicaemia, proven

**cephazolin 500 mg injection, 5 vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1256D NP | 2 | .. | .. | *17.39 | 18.60 | Cefazolin-AFT [AE] |

**cephazolin 2 g injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9326W NP | 10 | .. | .. | *38.85 | 38.80 | Cephazolin Alphapharm [AF] |

## ▪ CEPHAZOLIN

**Note** For item codes 1257E and 1797N, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

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

**Restricted benefit**
Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent
**Restricted benefit**
Septicaemia, suspected
**Restricted benefit**
Septicaemia, proven

**cephazolin 1 g injection, 5 vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1797N NP | 2 | .. | .. | *20.87 | 22.08 | [a] Cefazolin-AFT [AE] | [a] Hospira Cefazolin Sodium [PF] |

**cephazolin 1 g injection, 10 vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1257E NP | 1 | .. | .. | 20.87 | 22.08 | [a] Cefazolin Sandoz [SZ] |

*Second-generation cephalosporins*

## ▪ CEFACLOR

**Caution** Serum sickness-like reactions have been reported with this drug, especially in children.

**cefaclor 250 mg/5 mL powder for oral liquid, 75 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2461M | ‡1 | 1 | .. | #17.38 | 18.95 | [a] Aclor 250 [QA]<br>[a] Keflor [AF] | [a] APO-Cefaclor [TX] |
| | | | [B]5.31 | #22.69 | 18.95 | [a] Ceclor [AS] | |

**cefaclor 250 mg/5 mL powder for oral liquid, 75 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5047P DP | ‡1 | .. | .. | #17.38 | 18.95 | [a] Aclor 250 [QA]<br>[a] Keflor [AF] | [a] APO-Cefaclor [TX] |
| | | | [B]5.31 | #22.69 | 18.95 | [a] Ceclor [AS] | |

**cefaclor 125 mg/5 mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2460L | ‡1 | 1 | .. | #17.16 | 18.73 | [a] Aclor 125 [QA]<br>[a] Keflor [AF] | [a] APO-Cefaclor [TX] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | [B]5.10 | #22.26 | 18.73 | [a] Ceclor [AS] | |

**cefaclor 125 mg/5 mL powder for oral liquid, 100 mL**

| 5046N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | ‡1 | .. | .. | #17.16 | 18.73 | [a] Aclor 125 [QA]<br>[a] Keflor [AF] | [a] APO-Cefaclor [TX] |
| | | | [B]5.10 | #22.26 | 18.73 | [a] Ceclor [AS] | |

**cefaclor 375 mg modified release tablet, 10**

| 1169M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 14.42 | 15.63 | [a] APO-Cefaclor CD [TX]<br>[a] Cefaclor GH [GQ]<br>[a] Keflor CD [AF] | [a] Cefaclor-GA [EA]<br>[a] Karlor CD [LN]<br>[a] Ozcef [RA] |
| | | | [B]6.26 | 20.68 | 15.63 | [a] Ceclor CD [AS] | |

**cefaclor 375 mg modified release tablet, 10**

| 5045M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 14.42 | 15.63 | [a] APO-Cefaclor CD [TX]<br>[a] Cefaclor GH [GQ]<br>[a] Keflor CD [AF] | [a] Cefaclor-GA [EA]<br>[a] Karlor CD [LN]<br>[a] Ozcef [RA] |
| | | | [B]6.26 | 20.68 | 15.63 | [a] Ceclor CD [AS] | |

## ▪ CEFUROXIME

**cefuroxime 250 mg tablet, 14**

| 5052X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 21.18 | 22.39 | [a] Pharmacor Cefuroxime [CR] | [a] Zinnat [AS] |

**cefuroxime 250 mg tablet, 14**

| 8292K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 21.18 | 22.39 | [a] Pharmacor Cefuroxime [CR] | [a] Zinnat [AS] |

**CEFUROXIME AXETIL Powder for oral suspension 125 mg (base) per 5 mL, 70 mL, 1**

| 2002J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | ‡1 | .. | .. | #22.42 | 23.99 | Zinnat [AS] |

**CEFUROXIME AXETIL Powder for oral suspension 125 mg (base) per 5 mL, 70 mL, 1**

| 5499K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | #22.42 | 23.99 | Zinnat [AS] |

*Third-generation cephalosporins*

## ▪ CEFOTAXIME

**Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**CEFOTAXIME Powder for injection 1 g, 10**

| 1768C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 23.88 | 25.09 | Hospira Pty Limited [PF] |

## ▪ CEFOTAXIME

**Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**CEFOTAXIME Powder for injection 2 g, 10**

| 1769D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 34.74 | 35.95 | Hospira Pty Limited [PF] |

## ▪ CEFOTAXIME

**Note Shared Care Model**:

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

**Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

**CEFOTAXIME Powder for injection 2 g, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1759N NP | 1 | .. | .. | 34.74 | 35.95 | Hospira Pty Limited [PF] |

**CEFOTAXIME Powder for injection 1 g, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1758M NP | 1 | .. | .. | 23.88 | 25.09 | Hospira Pty Limited [PF] |

## ▪ CEFTRIAXONE

**Restricted benefit**

Gonorrhoea

**ceftriaxone 500 mg injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9058R NP | 1 | .. | .. | 12.15 | 13.36 | Ceftriaxone-AFT [AE] |

## ▪ CEFTRIAXONE

**Note Shared Care Model**:

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

**Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

**ceftriaxone 500 mg injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1783W NP | 5 | .. | .. | *16.40 | 17.61 | Ceftriaxone-AFT [AE] |

## ▪ CEFTRIAXONE

**Note** Pharmaceutical benefits that have the form ceftriaxone 2 g injection, 1 vial and pharmaceutical benefits that have the form ceftriaxone 2 g injection, 5 vials are equivalent for the purposes of substitution.

**Note Shared Care Model**:

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

**Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

**ceftriaxone 2 g injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1785Y NP | 5 | .. | .. | *22.25 | 23.46 | [a] Ceftriaxone-AFT [AE] |

**ceftriaxone 2 g injection, 5 vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11169W NP | 1 | .. | .. | 22.22 | 23.43 | [a] Ceftriaxone Alphapharm [AF] |

## ▪ CEFTRIAXONE

**Note** For item codes 1784X and 1788D, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

**Note Shared Care Model**:

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

**Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

**CEFTRIAXONE Powder for injection 1 g, 5**

| 1788D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 22.11 | 23.32 | [a] Ceftriaxone Alphapharm [AF] |

**ceftriaxone 1 g injection, 1 vial**

| 1784X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 5 | .. | .. | *22.10 | 23.31 | [a] Ceftriaxone-AFT [AE]<br>[a] Hospira Ceftriaxone [PF] | [a] Ceftriaxone Sandoz [SZ] |

*Fourth-generation cephalosporins*

## ▪ CEFEPIME

**Note Shared Care Model**:

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

**Authority required**

Febrile neutropenia

**CEFEPIME Powder for injection 1 g (as hydrochloride), 1**

| 8315P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 10 | .. | .. | *79.35 | 38.80 | [a] Cefepime-AFT [AE]<br>[a] Cefepime Kabi [PK]<br>[a] Omegapharm Pty Ltd [OE] | [a] Cefepime Alphapharm [AF]<br>[a] DBL Cefepime [PF] |

**CEFEPIME Powder for injection 2 g (as hydrochloride), 1**

| 8316Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 10 | .. | .. | *129.55 | 38.80 | [a] Cefepime-AFT [AE]<br>[a] Cefepime Kabi [PK]<br>[a] Omegapharm Pty Ltd [OE] | [a] Cefepime Alphapharm [AF]<br>[a] DBL Cefepime [PF] |

## SULFONAMIDES AND TRIMETHOPRIM

*Trimethoprim and derivatives*

## ▪ TRIMETHOPRIM

**trimethoprim 300 mg tablet, 7**

| 2922T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 12.79 | 14.00 | [a] Alprim [AF] |
| | | | [B]3.68 | 16.47 | 14.00 | [a] Triprim [RW] |

## ▪ TRIMETHOPRIM

**Authority required (STREAMLINED)**

***4243***

Prophylaxis of urinary tract infection

**trimethoprim 300 mg tablet, 7**

| 2666H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 2 | .. | *14.49 | 15.70 | [a] Alprim [AF] |
| | | | [B]7.36 | *21.85 | 15.70 | [a] Triprim [RW] |

## ▪ TRIMETHOPRIM

**Restricted benefit**

Prostatitis

**trimethoprim 300 mg tablet, 7**

| 10785P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | .. | .. | *17.91 | 19.12 | [a] Alprim [AF] |
| | | | [B]14.72 | *32.63 | 19.12 | [a] Triprim [RW] |

*Combinations of sulfonamides and trimethoprim, incl. derivatives*

## ▪ TRIMETHOPRIM + SULFAMETHOXAZOLE

**Caution** There is an increased risk of severe adverse reactions with this combination in the elderly.

**trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10**

| 2951H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 12.98 | 14.19 | [a] Resprim Forte [AF] |

| | | | | | |
|---|---|---|---|---|---|
| [B]2.17 | 15.15 | 14.19 | [a] Bactrim DS [RO] | | |
| [B]4.17 | 17.15 | 14.19 | [a] Septrin Forte [RW] | | |

**trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10**

3390K DP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 12.98 | 14.19 | [a] Resprim Forte [AF] |
| | | [B]2.17 | 15.15 | 14.19 | [a] Bactrim DS [RO] |
| | | [B]4.17 | 17.15 | 14.19 | [a] Septrin Forte [RW] |

**trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL**

3103H NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 13.27 | 14.48 | Bactrim [RO] |
| | | [B]5.69 | 18.96 | 14.48 | Septrin [RW] |

**trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL**

3391L DP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 13.27 | 14.48 | Bactrim [RO] |
| | | [B]5.69 | 18.96 | 14.48 | Septrin [RW] |

## ▪ TRIMETHOPRIM + SULFAMETHOXAZOLE

**Caution** There is an increased risk of severe adverse reactions with this combination in the elderly.

**Authority required (STREAMLINED)**

***6201***

Prophylaxis of Pneumocystis jiroveci pneumonia

**trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10**

10784N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 2 | .. | *16.75 | 17.96 | [a] Resprim Forte [AF] |
| | | [B]6.51 | *23.26 | 17.96 | [a] Bactrim DS [RO] |
| | | [B]12.51 | *29.26 | 17.96 | [a] Septrin Forte [RW] |

# MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

*Macrolides*

## ▪ AZITHROMYCIN

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

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

**Restricted benefit**

Trachoma

**azithromycin 200 mg/5 mL powder for oral liquid, 15 mL**

8201P NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | #26.26 | 27.83 | Zithromax [PF] |

**azithromycin 500 mg tablet, 2**

8336R NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 15.37 | 16.58 | [a] APO-Azithromycin [TX] | [a] Azithromycin-GA [EA] |
| | | | | | [a] Azithromycin Mylan [AF] | [a] Azithromycin Sandoz [SZ] |
| | | | | | [a] Chem mart Azithromycin [CH] | [a] Terry White Chemists Azithromycin [TW] |
| | | | | | [a] Zithromax [PF] | |

## ▪ AZITHROMYCIN

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

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

**Restricted benefit**

Urethritis

**Clinical criteria:**

- The condition must be uncomplicated and due to Chlamydia trachomatis.

**Restricted benefit**

Cervicitis

**Clinical criteria:**

- The condition must be uncomplicated and due to Chlamydia trachomatis.

**azithromycin 500 mg tablet, 2**

8200N NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 15.37 | 16.58 | [a] APO-Azithromycin [TX] | [a] Azithromycin-GA [EA] |
| | | | | | [a] Azithromycin Mylan [AF] | [a] Azithromycin Sandoz [SZ] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Chem mart Azithromycin [CH] | [a] Terry White Chemists Azithromycin [TW] |
| | | | | | | [a] Zithromax [PF] | |

## ▪ CLARITHROMYCIN

### clarithromycin 250 mg tablet, 14

| 8318T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 14.05 | 15.26 | [a] APO-Clarithromycin [TX] | [a] Chem mart Clarithromycin [CH] |
| | | | | | | [a] Clarac [ED] | [a] Clarihexal [HX] |
| | | | | | | [a] Clarithro 250 [RW] | [a] Clarithromycin AN [EA] |
| | | | | | | [a] Clarithromycin Sandoz [SZ] | [a] Kalixocin [AF] |
| | | | | | | [a] Terry White Chemists Clarithromycin [TW] | |
| | | | [B]3.49 | 17.54 | 15.26 | [a] Klacid [GO] | |

## ▪ CLARITHROMYCIN

**Restricted benefit**

Bordetella pertussis

**Restricted benefit**

Atypical mycobacterial infections

### clarithromycin 250 mg/5 mL powder for oral liquid, 50 mL

| 9192T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | .. | .. | #29.93 | 31.50 | Klacid [GO] |

## ▪ ERYTHROMYCIN

### erythromycin 250 mg enteric capsule, 25

| 1404X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 15.87 | 17.08 | [a] Mayne Pharma Erythromycin [YT] |
| | | | [B]2.53 | 18.40 | 17.08 | [a] Eryc [YN] |

### erythromycin 250 mg enteric capsule, 25

| 3325B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 15.87 | 17.08 | [a] Mayne Pharma Erythromycin [YT] |
| | | | [B]2.53 | 18.40 | 17.08 | [a] Eryc [YN] |

## ▪ ERYTHROMYCIN

**Authority required (STREAMLINED)**

***6160***

Severe acne

**Clinical criteria:**

- The condition must be one in which tetracycline therapy is inappropriate.

### erythromycin 250 mg enteric capsule, 25

| 10780J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *20.65 | 21.86 | [a] Mayne Pharma Erythromycin [YT] |
| | | | [B]5.06 | *25.71 | 21.86 | [a] Eryc [YN] |

## ▪ ERYTHROMYCIN ETHYLSUCCINATE

### erythromycin (as ethylsuccinate) 200 mg/5 mL powder for oral liquid, 100 mL

| 2424N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | .. | #18.62 | 20.19 | [a] E-Mycin 200 [AF] |
| | | | [B]2.36 | #20.98 | 20.19 | [a] E.E.S. 200 [GH] |

### erythromycin (as ethylsuccinate) 200 mg/5 mL powder for oral liquid, 100 mL

| 3334L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | ‡1 | .. | .. | #18.62 | 20.19 | [a] E-Mycin 200 [AF] |
| | | | [B]2.36 | #20.98 | 20.19 | [a] E.E.S. 200 [GH] |

### erythromycin (as ethylsuccinate) 400 mg tablet, 25

| 2750R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 15.99 | 17.20 | E-Mycin [AF] |

**erythromycin (as ethylsuccinate) 400 mg tablet, 25**

| 3336N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 15.99 | 17.20 | E-Mycin [AF] |

**erythromycin (as ethylsuccinate) 400 mg/5 mL powder for oral liquid, 100 mL**

| 2428T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | .. | #19.93 | 21.50 | [a] E-Mycin 400 [AF] |
| | | | [B]2.38 | #22.31 | 21.50 | [a] E.E.S. Granules [GH] |

**erythromycin (as ethylsuccinate) 400 mg/5 mL powder for oral liquid, 100 mL**

| 3337P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | ‡1 | .. | .. | #19.93 | 21.50 | [a] E-Mycin 400 [AF] |
| | | | [B]2.38 | #22.31 | 21.50 | [a] E.E.S. Granules [GH] |

## ▪ ERYTHROMYCIN ETHYLSUCCINATE

**Authority required (STREAMLINED)**

***6160***

Severe acne

**Clinical criteria:**

- The condition must be one in which tetracycline therapy is inappropriate.

**erythromycin (as ethylsuccinate) 400 mg tablet, 25**

| 10789W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *20.89 | 22.10 | E-Mycin [AF] |

## ▪ ROXITHROMYCIN

**roxithromycin 50 mg dispersible tablet, 10**

| 5259T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 16.72 | 17.93 | Rulide D [SW] |

**roxithromycin 50 mg dispersible tablet, 10**

| 8129W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 16.72 | 17.93 | Rulide D [SW] |

**roxithromycin 300 mg tablet, 5**

| 5261X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 13.57 | 14.78 | [a] APO-Roxithromycin [TX] | [a] Biaxsig [AV] |
| | | | | | | [a] Chem mart Roxithromycin [CH] | [a] Roxar 300 [RW] |
| | | | | | | [a] Roximycin [AF] | [a] Roxithromycin AN [EA] |
| | | | | | | [a] Roxithromycin-GA [ED] | [a] Roxithromycin GH [GQ] |
| | | | | | | [a] Roxithromycin Sandoz [SZ] | [a] Terry White Chemists Roxithromycin [TW] |
| | | | [B]1.62 | 15.19 | 14.78 | [a] Rulide [SW] | |

**roxithromycin 300 mg tablet, 5**

| 8016X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 13.57 | 14.78 | [a] APO-Roxithromycin [TX] | [a] Biaxsig [AV] |
| | | | | | | [a] Chem mart Roxithromycin [CH] | [a] Roxar 300 [RW] |
| | | | | | | [a] Roximycin [AF] | [a] Roxithromycin AN [EA] |
| | | | | | | [a] Roxithromycin-GA [ED] | [a] Roxithromycin GH [GQ] |
| | | | | | | [a] Roxithromycin Sandoz [SZ] | [a] Terry White Chemists Roxithromycin [TW] |
| | | | [B]1.62 | 15.19 | 14.78 | [a] Rulide [SW] | |

**roxithromycin 150 mg tablet, 10**

| 1760P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 13.57 | 14.78 | [a] APO-Roxithromycin [TX] | [a] Biaxsig [AV] |
| | | | | | | [a] Chem mart Roxithromycin [CH] | [a] Roxar 150 [RW] |
| | | | | | | [a] Roximycin [AF] | [a] Roxithromycin AN [EA] |
| | | | | | | [a] Roxithromycin-GA [ED] | [a] Roxithromycin GH [GQ] |
| | | | | | | [a] Roxithromycin Sandoz [SZ] | [a] Terry White Chemists Roxithromycin [TW] |
| | | | [B]1.62 | 15.19 | 14.78 | [a] Rulide [SW] | |

**roxithromycin 150 mg tablet, 10**

| 5260W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 13.57 | 14.78 | [a] APO-Roxithromycin [TX]<br>[a] Chem mart Roxithromycin [CH]<br>[a] Roximycin [AF]<br>[a] Roxithromycin-GA [ED]<br>[a] Roxithromycin Sandoz [SZ] | [a] Biaxsig [AV]<br>[a] Roxar 150 [RW]<br>[a] Roxithromycin AN [EA]<br>[a] Roxithromycin GH [GQ]<br>[a] Terry White Chemists Roxithromycin [TW] |
| | | | [B]1.62 | 15.19 | 14.78 | [a] Rulide [SW] | |

*Lincosamides*

## ▪ CLINDAMYCIN

**Restricted benefit**

Gram-positive coccal infections

**Clinical criteria:**

- The condition must not be able to be safely and effectively treated with a penicillin.

**clindamycin 150 mg capsule, 24**

| 5057E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 17.96 | 19.17 | [a] APO-Clindamycin [TX]<br>[a] Chem mart Clindamycin [CH]<br>[a] Clindamycin BNM [BZ]<br>[a] Clindamyk [AF] | [a] Calindamin [RW]<br>[a] Cleocin [FZ]<br>[a] Clindamycin-Link [LM]<br>[a] Terry White Chemists Clindamycin [TW] |
| | | | [B]8.60 | 26.56 | 19.17 | [a] Dalacin C [PF] | |

## ▪ CLINDAMYCIN

**Restricted benefit**

Gram-positive coccal infections

**Clinical criteria:**

- The condition must not be able to be safely and effectively treated with a penicillin.

**clindamycin 150 mg capsule, 24**

| 3138E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 2 | 1 | .. | *24.83 | 26.04 | [a] APO-Clindamycin [TX]<br>[a] Chem mart Clindamycin [CH]<br>[a] Clindamycin BNM [BZ]<br>[a] Clindamyk [AF] | [a] Calindamin [RW]<br>[a] Cleocin [FZ]<br>[a] Clindamycin-Link [LM]<br>[a] Terry White Chemists Clindamycin [TW] |
| | | | [B]17.20 | *42.03 | 26.04 | [a] Dalacin C [PF] | |

## ▪ LINCOMYCIN

**lincomycin 600 mg/2 mL injection, 5 x 2 mL vials**

| 2530E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 1 | .. | .. | 142.86 | 38.80 | Lincocin [PF] |

**lincomycin 600 mg/2 mL injection, 5 x 2 mL vials**

| 5144R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 142.86 | 38.80 | Lincocin [PF] |

# AMINOGLYCOSIDE ANTIBACTERIALS

*Other aminoglycosides*

## ▪ GENTAMICIN

**gentamicin 80 mg/2 mL injection, 10 x 2 mL ampoules**

| 2824P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 22.61 | 23.82 | Pfizer Australia Pty Ltd [PF] |

## ▪ TOBRAMYCIN

**Restricted benefit**

Pseudomonas aeruginosa infection

**Clinical criteria:**

- Patient must have cystic fibrosis, **AND**
- The treatment must be systemic.

**tobramycin 500 mg/5 mL injection, 10 x 5 mL vials**

| 9480Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 279.78 | 38.80 | Tobra-Day [PL] |

## ▪ TOBRAMYCIN

**Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

**tobramycin 80 mg/2 mL injection, 5 x 2 mL vials**

| 1356J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 1 | .. | *48.31 | 38.80 | [a] Hospira Pty Limited [PF] | [a] Tobramycin Mylan [AF] |

**tobramycin Injection 80 mg (base) in 2 mL (without preservative), 5**

| 8872Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 1 | .. | *48.31 | 38.80 | Pfizer Australia Pty Ltd [PF] |

## ▪ TOBRAMYCIN

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

**Authority required (STREAMLINED)**

***4456***

Proven Pseudomonas aeruginosa infection

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have cystic fibrosis, **AND**
- Patient must have been assessed for bronchial hyperresponsiveness as per the TGA-approved Product Information, with a negative test result, **AND**
- Patient must be participating in a four week trial of tobramycin inhalation powder and will be assessed for ability to tolerate the dry powder formulation in order to qualify for continued PBS-subsidised therapy. The trial commencement date must be documented in the patient's medical records.

**Population criteria:**

- Patient must be 6 years of age or older.

**tobramycin 28 mg powder for inhalation, 224 capsules**

| 10066T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 2432.37 | 38.80 | TOBI podhaler [NV] |

## ▪ TOBRAMYCIN

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

**Authority required (STREAMLINED)**

***4513***

Proven Pseudomonas aeruginosa infection

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have cystic fibrosis, **AND**
- Patient must have previously been issued with an authority prescription for tobramycin inhalation capsules, **AND**
- Patient must have demonstrated ability to tolerate the dry powder formulation following the initial 4-week treatment period, as agreed by the patient, the patient's family (in the case of paediatric patients) and the treating physician(s).

**Population criteria:**

- Patient must be 6 years of age or older.

**tobramycin 28 mg powder for inhalation, 224 capsules**

| 10074F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 2432.37 | 38.80 | TOBI podhaler [NV] |

## ▪ TOBRAMYCIN

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

**Authority required (STREAMLINED)**

***5520***

Proven Pseudomonas aeruginosa infection

**Clinical criteria:**

- Patient must have cystic fibrosis, **AND**
- The treatment must be for management.

**tobramycin 300 mg/5 mL inhalation solution, 56 x 5 mL ampoules**

5442K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 1048.47 | 38.80 | [a] Tobi [NV] | [a] Tobramycin AN [EA] |

## QUINOLONE ANTIBACTERIALS

*Fluoroquinolones*

### ▪ CIPROFLOXACIN

**Authority required**

Respiratory tract infection

**Clinical criteria:**

- The condition must be proven or suspected to be caused by Pseudomonas aeruginosa, **AND**
- Patient must be severely immunocompromised.

**Authority required**

Bacterial gastroenteritis

**Clinical criteria:**

- Patient must be severely immunocompromised.

**Authority required**

Infection

**Clinical criteria:**

- The condition must be proven to be due to Pseudomonas aeruginosa resistant to all other oral antimicrobials; OR
- The condition must be proven to be due to other gram-negative bacteria resistant to all other oral antimicrobials.

**Authority required**

Bone or joint infection

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Epididymo-orchitis

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Prostatitis

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Perichondritis of the pinna

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**ciprofloxacin 500 mg tablet, 14**

1209P

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 17.35 | 18.56 | [a] APO-Ciprofloxacin [TX] | [a] C-Flox 500 [AL] |
| | | | | | [a] Cifran [RA] | [a] Ciprofloxacin AN [EA] |
| | | | | | [a] Ciprofloxacin-BW [GQ] | [a] Ciprofloxacin Sandoz [SZ] |
| | | | | | [a] Ciprol 500 [RW] | [a] Loxip 500 [DO] |
| | | [B]2.43 | 19.78 | 18.56 | [a] Ciproxin 500 [BN] | |

**ciprofloxacin 750 mg tablet, 14**

1210Q NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 20.52 | 21.73 | [a] APO-Ciprofloxacin [TX]<br>[a] Cifran [RA]<br>[a] Ciprofloxacin-BW [GQ]<br>[a] Ciprol 750 [RW] | [a] C-Flox 750 [AL]<br>[a] Ciprofloxacin AN [EA]<br>[a] Ciprofloxacin Sandoz [SZ]<br>[a] Loxip 750 [DO] |

## ▪ CIPROFLOXACIN

**Authority required**

Respiratory tract infection

**Clinical criteria:**

- The condition must be proven or suspected to be caused by Pseudomonas aeruginosa, **AND**
- Patient must be severely immunocompromised.

**Authority required**

Bacterial gastroenteritis

**Clinical criteria:**

- Patient must be severely immunocompromised.

**Authority required**

Infection

**Clinical criteria:**

- The condition must be proven to be due to Pseudomonas aeruginosa resistant to all other oral antimicrobials; OR
- The condition must be proven to be due to other gram-negative bacteria resistant to all other oral antimicrobials.

**Authority required**

Bone or joint infection

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Epididymo-orchitis

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Prostatitis

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Perichondritis of the pinna

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Gonorrhoea

**ciprofloxacin 250 mg tablet, 14**

1208N NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 14.29 | 15.50 | [a] APO-Ciprofloxacin [TX]<br>[a] Ciprofloxacin Sandoz [SZ] | [a] C-Flox 250 [AL]<br>[a] Ciprol 250 [RW] |
| | | [B]1.74 | 16.03 | 15.50 | [a] Ciproxin 250 [BN] | |

## ▪ NORFLOXACIN

**Authority required**

Acute bacterial enterocolitis

**Authority required**

Complicated urinary tract infection

**norfloxacin 400 mg tablet, 14**

3010K NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 14.67 | 15.88 | [a] GenRx Norfloxacin [GX] | [a] Nufloxib [AF] |

[a] Roxin [RW]

## OTHER ANTIBACTERIALS

*Glycopeptide antibacterials*

### ▪ VANCOMYCIN

**Restricted benefit**

Endocarditis

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be hypersensitive to penicillin.

**vancomycin 500 mg injection, 1 vial**

3130R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | .. | .. | *16.81 | 18.02 | [a] Hospira Pty Limited [PF] | [a] Vancomycin Alphapharm [AF] |

**vancomycin 1 g injection, 1 vial**

2269K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 15.92 | 17.13 | [a] Hospira Pty Limited [PF]<br>[a] Vycin IV [EA] | [a] Vancomycin Alphapharm [AF] |

### ▪ VANCOMYCIN

**Restricted benefit**

Endocarditis

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be hypersensitive to penicillin.

**vancomycin 500 mg injection, 1 vial**

3323X DP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | .. | .. | *16.81 | 18.02 | [a] Hospira Pty Limited [PF] | [a] Vancomycin Alphapharm [AF] |

**vancomycin 1 g injection, 1 vial**

5083M DP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 15.92 | 17.13 | [a] Hospira Pty Limited [PF]<br>[a] Vycin IV [EA] | [a] Vancomycin Alphapharm [AF] |

### ▪ VANCOMYCIN

**Restricted benefit**

Endophthalmitis

**Restricted benefit**

Infection

**Clinical criteria:**

- The treatment must be initiated in a hospital, **AND**
- The condition must be one in which vancomycin is an appropriate antibiotic.

**vancomycin 500 mg injection, 1 vial**

3131T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5 | .. | .. | *25.40 | 26.61 | [a] Hospira Pty Limited [PF] | [a] Vancomycin Alphapharm [AF] |

**vancomycin 1 g injection, 1 vial**

2270L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | .. | .. | *25.57 | 26.78 | [a] Hospira Pty Limited [PF]<br>[a] Vycin IV [EA] | [a] Vancomycin Alphapharm [AF] |

*Steroid antibacterials*

### ▪ FUSIDATE

**Restricted benefit**

Serious staphylococcal infections

**Clinical criteria:**

- The treatment must be used in combination with another antibiotic, **AND**
- The condition must be proven to be due to a staphylococcus.

**sodium fusidate 250 mg tablet, 36**

2312Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 84.04 | 38.80 | Fucidin [CS] |

## ▪ FUSIDATE

**Authority required (STREAMLINED)**

***6133***

Osteomyelitis

**Clinical criteria:**

- The condition must be methicillin-resistant staphylococcal aureus (MRSA), **AND**
- The treatment must be used in combination with other anti-staphylococcal antibiotics.

**sodium fusidate 250 mg tablet, 36**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10782L | 2 | 1 | .. | *156.99 | 38.80 | Fucidin [CS] |

*Imidazole derivatives*

## ▪ METRONIDAZOLE

**metronidazole 500 mg suppository, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1642K NP | ‡1 | .. | .. | 25.65 | 26.86 | Flagyl [SW] |

**metronidazole 500 mg suppository, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5157K DP | ‡1 | .. | .. | 25.65 | 26.86 | Flagyl [SW] |

**metronidazole 200 mg/5 mL oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1630T NP | ‡1 | .. | .. | 21.87 | 23.08 | Flagyl S [SW] |

**metronidazole 200 mg/5 mL oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3341W DP | ‡1 | .. | .. | 21.87 | 23.08 | Flagyl S [SW] |

**metronidazole 200 mg tablet, 21**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1636D NP | 1 | 1 | .. | 12.36 | 13.57 | [a] Metrogyl 200 [AF] | [a] Metronide 200 [AV] |
| | | | [B]2.00 | 14.36 | 13.57 | [a] Flagyl [SW] | |

**metronidazole 200 mg tablet, 21**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3339R DP | 1 | .. | .. | 12.36 | 13.57 | [a] Metrogyl 200 [AF] | [a] Metronide 200 [AV] |
| | | | [B]2.00 | 14.36 | 13.57 | [a] Flagyl [SW] | |

## ▪ METRONIDAZOLE

**Restricted benefit**

Anaerobic infections

**metronidazole 400 mg tablet, 21**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1621H NP | 1 | 1 | .. | 14.07 | 15.28 | [a] Metrogyl 400 [AF] | [a] Metronide 400 [AV] |
| | | | [B]2.00 | 16.07 | 15.28 | [a] Flagyl [SW] | |

## ▪ METRONIDAZOLE

**Restricted benefit**

Acute anaerobic sepsis

**Treatment criteria:**

- Must be treated in a hospital.

**metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1832K DP | 1 | .. | .. | 20.81 | 22.02 | Metronidazole Sandoz IV [SZ] |

## ▪ METRONIDAZOLE

**Restricted benefit**

Anaerobic infections

**metronidazole 400 mg tablet, 21**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5155H DP | 1 | .. | .. | 14.07 | 15.28 | [a] Metrogyl 400 [AF] | [a] Metronide 400 [AV] |

| | | | | |
|---|---|---|---|---|
| [B]2.00 | 16.07 | 15.28 | [a] | Flagyl [SW] |

## ▪ METRONIDAZOLE

**Restricted benefit**

Prophylaxis to prevent infection

**Clinical criteria:**

- Patient must be undergoing large bowel surgery.

**Restricted benefit**

Acute anaerobic sepsis

**Treatment criteria:**

- Must be treated in a hospital.

**metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags**

| 1821W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 20.81 | 22.02 | Metronidazole Sandoz IV [SZ] |

## ▪ TINIDAZOLE

**tinidazole 500 mg tablet, 4**

| 1465D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 14.89 | 16.10 | [a] Simplotan [FZ] |
| | | | [B]6.70 | 21.59 | 16.10 | [a] Fasigyn [PF] |

*Nitrofuran derivatives*

## ▪ NITROFURANTOIN

**Caution** Nitrofurantoin may cause peripheral neuritis and severe pulmonary reactions.

**nitrofurantoin 100 mg capsule, 30**

| 1693D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | .. | 32.12 | 33.33 | Macrodantin [PF] |

**nitrofurantoin 50 mg capsule, 30**

| 1692C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | .. | 26.08 | 27.29 | Macrodantin [PF] |

*Other antibacterials*

## ▪ HEXAMINE HIPPURATE

**hexamine hippurate 1 g tablet, 100**

| 3124K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 44.11 | 38.80 | Hiprex [IA] |

# ▪ ANTIMYCOTICS FOR SYSTEMIC USE

## ANTIMYCOTICS FOR SYSTEMIC USE

*Triazole derivatives*

## ▪ FLUCONAZOLE

**Note Shared Care Model**:

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

**Restricted benefit**

Cryptococcal meningitis

**Restricted benefit**

Cryptococcal meningitis

**Clinical criteria:**

- The treatment must be maintenance therapy, **AND**
- Patient must be immunosuppressed.

**Restricted benefit**

Oropharyngeal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Restricted benefit**

Oesophageal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Restricted benefit**

Oropharyngeal candidiasis

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be immunosuppressed.

**Restricted benefit**

Candida infections

**Clinical criteria:**

- The condition must be serious or life-threatening.

**fluconazole 200 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1475P NP | 1 | 5 | .. | 51.46 | 38.80 | [a] APO-Fluconazole [TX]<br>[a] Dizole 200 [AF]<br>[a] Fluzole 200 [RW] | [a] Diflucan [PF]<br>[a] Fluconazole Sandoz [SZ]<br>[a] Ozole [RA] |

**fluconazole 100 mg/50 mL injection, 50 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1473M NP | 7 | .. | .. | *21.08 | 22.29 | Fluconazole Sandoz [SZ] |

**fluconazole 100 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1472L NP | 1 | 5 | .. | 31.81 | 33.02 | [a] Diflucan [PF]<br>[a] Fluconazole Sandoz [SZ] | [a] Dizole 100 [AF]<br>[a] Ozole [RA] |

**fluconazole 400 mg/200 mL injection, 200 mL bag**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1757L NP | 1 | .. | .. | 15.33 | 16.54 | Fluconazole Alphapharm [AF] |

**fluconazole 50 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1471K NP | 1 | 5 | .. | 21.73 | 22.94 | [a] Dizole 50 [AF]<br>[a] Ozole [RA] | [a] Fluconazole Sandoz [SZ] |
| | | | [B]2.94 | 24.67 | 22.94 | [a] Diflucan [PF] | |

## ▪ FLUCONAZOLE

**Note Shared Care Model**:

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

**Restricted benefit**

Cryptococcal meningitis

**Clinical criteria:**

- Patient must be unable to take a solid dose form of fluconazole.

**Restricted benefit**

Cryptococcal meningitis

**Clinical criteria:**

- The treatment must be maintenance therapy, **AND**
- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**Restricted benefit**

Oropharyngeal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**Restricted benefit**

Oesophageal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**Restricted benefit**

Oropharyngeal candidiasis

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**Restricted benefit**

Candida infections

**Clinical criteria:**

- The condition must be serious or life-threatening, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**fluconazole 50 mg/5 mL powder for oral liquid, 35 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5446P NP | 1 | .. | .. | #67.36 | 38.80 | Diflucan [PF] |

## ▪ FLUCONAZOLE

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

**Note** Pharmaceutical benefits that have the forms fluconazole 200 mg/100 mL injection, 100 mL vial and fluconazole 200 mg/100 mL injection, 100 mL bag are equivalent for the purposes of substitution.

**Restricted benefit**

Cryptococcal meningitis

**Restricted benefit**

Cryptococcal meningitis

**Clinical criteria:**

- The treatment must be maintenance therapy, **AND**
- Patient must be immunosuppressed.

**Restricted benefit**

Oropharyngeal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Restricted benefit**

Oesophageal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Restricted benefit**

Oropharyngeal candidiasis

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be immunosuppressed.

**Restricted benefit**

Candida infections

**Clinical criteria:**

- The condition must be serious or life-threatening.

**fluconazole 200 mg/100 mL injection, 100 mL bag**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11139G NP | 7 | .. | .. | *46.35 | 38.80 | [a] Fluconazole Alphapharm [AF] |

**fluconazole 200 mg/100 mL injection, 100 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1474N NP | 7 | .. | .. | *46.35 | 38.80 | [a] Fluconazole Sandoz [SZ] |

## ▪ ITRACONAZOLE

**Note** One capsule of itraconazole 50 mg (Lozanoc) is therapeutically equivalent to one 100 mg capsule of conventional itraconazole (Sporanox). The recommended dose of Lozanoc is therefore half the recommended dose for Sporanox. Lozanoc 50 mg capsules and Sporanox 100 mg capsules are not interchangeable.

**Note** Not for use in superficial mycoses

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

**Restricted benefit**

Systemic aspergillosis

**Restricted benefit**

Systemic sporotrichosis

**Restricted benefit**

Systemic histoplasmosis

**Restricted benefit**

Disseminated pulmonary histoplasmosis infection

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS).

**Restricted benefit**

Chronic pulmonary histoplasmosis infection

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS).

**Restricted benefit**

Oropharyngeal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Restricted benefit**

Oesophageal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**itraconazole 100 mg capsule, 60**

| 8196J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 128.66 | 38.80 | [a] APO-Itraconazole [TX]<br>[a] ITRANOX [RW] | [a] Itracap [AF]<br>[a] Sporanox [JC] |

**itraconazole 50 mg capsule, 60**

| 10732W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 128.66 | 38.80 | Lozanoc [YN] |

## ▪ POSACONAZOLE

**Note** Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

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

**Authority required**

Invasive aspergillosis

**Clinical criteria:**

- Patient must be unable to tolerate alternative therapy; OR
- Patient must have disease refractory to alternative therapy.

**Authority required**

Prophylaxis of invasive fungal infections including both yeasts and moulds

**Clinical criteria:**

- Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre), for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR
- Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or extensive chronic GVHD, and receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant.

Treatment of neutropenia should continue until recovery of the neutrophil count to at least 500 cells per cubic millimetre.

Patients who have had a previous invasive fungal infection should have secondary prophylaxis during subsequent episodes of neutropenia.

No more than 6 months therapy per episode will be PBS-subsidised

**Authority required**

Fungal infection

**Clinical criteria:**

- The condition must be fusariosis; OR
- The condition must be zygomycosis; OR
- The condition must be coccidioidomycosis; OR
- The condition must be chromoblastomycosis; OR
- The condition must be mycetoma, **AND**
- Patient must be unable to tolerate alternative therapy; OR
- Patient must have disease refractory to alternative therapy.

**posaconazole 100 mg modified release tablet, 24**

| 10460M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 834.65 | 38.80 | Noxafil [MK] |

## ▪ POSACONAZOLE

**Note** Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

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

**Authority required**

Invasive aspergillosis

**Clinical criteria:**

- Patient must be unable to tolerate alternative therapy; OR
- Patient must have disease refractory to alternative therapy.

**Authority required**

Fungal infection

**Clinical criteria:**

- The condition must be fusariosis; OR
- The condition must be zygomycosis; OR
- The condition must be coccidioidomycosis; OR
- The condition must be chromoblastomycosis; OR
- The condition must be mycetoma, **AND**
- Patient must be unable to tolerate alternative therapy; OR
- Patient must have disease refractory to alternative therapy.

**Authority required**

Prophylaxis of invasive fungal infections including both yeasts and moulds

**Clinical criteria:**

- Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre), for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR
- Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or extensive chronic GVHD, and receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant.

No more than 6 months therapy per episode will be PBS-subsidised

### posaconazole 40 mg/mL oral liquid, 105 mL

| 9360P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 691.97 | 38.80 | Noxafil [MK] |

## ▪ VORICONAZOLE

**Note** For patients with graft versus host disease, acute myeloid leukaemia or myelodysplastic syndrome, applications for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

**Note** For patients undergoing allogeneic haematopoietic stem cell transplant, applications for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 2 months' treatment may be authorised.

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

**Authority required**

Prophylaxis of invasive fungal infections including both yeasts and moulds

**Clinical criteria:**

- Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre) for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR
- Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or, extensive chronic GVHD, whilst receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant; OR
- Patient must be undergoing allogeneic haematopoietic stem cell transplant using either bone marrow from an unrelated donor or umbilical cord blood (related or unrelated), and, be considered to be at high risk of developing an invasive fungal infection during the neutropenic phase prior to engraftment.

### voriconazole 40 mg/mL powder for oral liquid, 70 mL

| 10168E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | #496.21 | 38.80 | Vfend [PF] |

### voriconazole 200 mg tablet, 56

| 10198R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 1590.34 | 38.80 | [a] Vfend [PF] | [a] Voriconazole APOTEX [TX] |
| | | | | | | [a] Voriconazole Sandoz [SZ] | [a] Vttack [AF] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Vzole [RW] | |

**voriconazole 50 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10173K NP | 1 | .. | .. | 411.53 | 38.80 | [a] Vfend [PF]<br>[a] Voriconazole Sandoz [SZ]<br>[a] Vzole [RW] | [a] Voriconazole APOTEX [TX]<br>[a] Vttack [AF] |

## ▪ VORICONAZOLE

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

**Authority required**
Definite or probable invasive aspergillosis
Treatment Phase: Treatment and maintenance therapy
**Clinical criteria:**
- Patient must be immunocompromised.

**Authority required**
Serious fungal infections
Treatment Phase: Treatment and maintenance therapy
**Clinical criteria:**
- The condition must be caused by Scedosporium species; OR
- The condition must caused by Fusarium species.

**Authority required**
Serious Candida infections
Treatment Phase: Treatment and maintenance therapy
**Clinical criteria:**
- The condition must be caused by species not susceptible to fluconazole; OR
- The condition must be resistant to fluconazole; OR
- Patient must be unable to tolerate fluconazole.

**Authority required**
Serious invasive mycosis infections
Treatment Phase: Treatment and maintenance therapy
**Clinical criteria:**
- The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.

**voriconazole 200 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9364W NP | 1 | 2 | .. | 1590.34 | 38.80 | [a] Vfend [PF]<br>[a] Voriconazole Sandoz [SZ]<br>[a] Vzole [RW] | [a] Voriconazole APOTEX [TX]<br>[a] Vttack [AF] |

**voriconazole 50 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9363T NP | 1 | 2 | .. | 411.53 | 38.80 | [a] Vfend [PF]<br>[a] Voriconazole Sandoz [SZ]<br>[a] Vzole [RW] | [a] Voriconazole APOTEX [TX]<br>[a] Vttack [AF] |

## ▪ VORICONAZOLE

**Note** Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

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

**Authority required**
Definite or probable invasive aspergillosis
Treatment Phase: Treatment and maintenance therapy
**Clinical criteria:**
- Patient must be immunocompromised.

**Authority required**
Serious fungal infections
Treatment Phase: Treatment and maintenance therapy
**Clinical criteria:**
- The condition must be caused by Scedosporium species; OR
- The condition must caused by Fusarium species.

**Authority required**

Serious Candida infections
Treatment Phase: Treatment and maintenance therapy
**Clinical criteria:**
- The condition must be caused by species not susceptible to fluconazole; OR
- The condition must be resistant to fluconazole; OR
- Patient must be unable to tolerate fluconazole.

**Authority required**
Serious invasive mycosis infections
Treatment Phase: Treatment and maintenance therapy
**Clinical criteria:**
- The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.

**voriconazole 40 mg/mL powder for oral liquid, 70 mL**

| 9452L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | #496.21 | 38.80 | Vfend [PF] |

# ANTIMYCOBACTERIALS

## DRUGS FOR TREATMENT OF TUBERCULOSIS

*Hydrazides*

### ISONIAZID

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

**isoniazid 100 mg tablet, 100**

| 1554T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 23.53 | 24.74 | Arrow Pharma Pty Ltd [RW] |

## DRUGS FOR TREATMENT OF LEPRA

*Drugs for treatment of lepra*

### DAPSONE

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

**dapsone 100 mg tablet, 100**

| 1272Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 353.02 | 38.80 | Link Medical Products Pty Ltd [LM] |

**dapsone 25 mg tablet, 100**

| 8801F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 288.57 | 38.80 | Link Medical Products Pty Ltd [LM] |

### RIFAMPICIN

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

**Authority required**
Leprosy
**Population criteria:**
- Patient must be an adult.

**rifampicin 300 mg capsule, 100**

| 1983J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 133.02 | 38.80 | Rimycin 300 [AF] |

**rifampicin 150 mg capsule, 100**

| 1982H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 281.44 | 38.80 | Rimycin 150 [AF] |

## ▪ RIFAMPICIN

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

**Restricted benefit**
Meningococcal disease
**Clinical criteria:**
- The treatment must be for prophylaxis, **AND**
- Patient must be a carrier of the disease; OR
- Patient must be in close contact with people who have the disease.

**Restricted benefit**
Haemophilus influenzae type B
**Clinical criteria:**
- The treatment must be for prophylaxis, **AND**
- Patient must be in contact with people who have the disease.

**rifampicin 150 mg capsule, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1981G NP | 1 | .. | .. | 37.82 | 38.80 | Rimycin 150 [AF] |

**rifampicin 100 mg/5 mL oral liquid, 60 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8025J NP | ‡1 | .. | .. | 30.85 | 32.06 | Rifadin [SW] |

**rifampicin 300 mg capsule, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1984K NP | 1 | .. | .. | 23.28 | 24.49 | Rimycin 300 [AF] |

# ▪ ANTIVIRALS FOR SYSTEMIC USE

## DIRECT ACTING ANTIVIRALS

*Nucleosides and nucleotides excl. reverse transcriptase inhibitors*

## ▪ ACICLOVIR

**Note** Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)**
***5942***
Recurrent moderate to severe genital herpes
Treatment Phase: Episodic treatment or suppressive therapy
Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**aciclovir 200 mg tablet, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1007B NP | 1 | 5 | .. | 35.63 | 36.84 | [a] Aciclovir 200 [CR]<br>[a] Aciclovir Sandoz [HX]<br>[a] GenRx Aciclovir [GX]<br>[a] Ozvir [RA] | [a] Aciclovir GH [GQ]<br>[a] Acyclo-V 200 [AF]<br>[a] Lovir [EA] |
| | | | [B]0.91 | 36.54 | 36.84 | [a] Zovirax 200 mg [GK] | |

## ▪ ACICLOVIR

**Note** This drug is only effective if commenced within 72 hours of onset of rash.
**Note** Aciclovir 800 mg is not PBS-subsidised for herpes simplex or chickenpox.
**Note** No applications for repeats will be authorised.

**Authority required (STREAMLINED)**
***5967***
Herpes zoster
**Clinical criteria:**
- The treatment must be administered within 72 hours of the onset of the rash.

**Authority required (STREAMLINED)**
***5959***
Herpes zoster ophthalmicus

**aciclovir 800 mg tablet, 35**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1052J NP | 1 | .. | .. | 40.79 | 38.80 | [a] Aciclovir 800 [CR] | [a] Aciclovir Sandoz [HX] |

[a] GenRx Aciclovir [GX]

## ▪ ACICLOVIR

**Note** Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

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

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

**Note** For item codes 1003T and 1555W, pharmaceutical benefits that have the form tablet 200 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

***5936***

Initial moderate to severe genital herpes

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

### aciclovir 200 mg tablet, 25

1003T (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *24.73 | 25.94 | [a] Aciclovir Sandoz [HX] |

### aciclovir 200 mg tablet, 50

1555W (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 24.72 | 25.93 | [a] GenRx Aciclovir [GX] |

## ▪ FAMCICLOVIR

**Note** Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)**

***5971***

Recurrent moderate to severe genital herpes

Treatment Phase: Suppressive therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

### famciclovir 250 mg tablet, 56

8217L (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 71.94 | 38.80 | [a] APO-Famciclovir [TX] | [a] Auro-Famciclovir 250 [DO] |
| | | | | | [a] Ezovir [AF] | [a] Famciclovir AN [EA] |
| | | | | | [a] Famciclovir FBM [FO] | [a] Famciclovir-GA [ED] |
| | | | | | [a] Famciclovir generichealth 250 [GQ] | [a] Famciclovir Sandoz [SZ] |
| | | | | | [a] Famciclovir SCP 250 [CR] | [a] Famlo [RA] |
| | | | | | [a] Famvir [HX] | [a] Favic 250 [RW] |

## ▪ FAMCICLOVIR

**Note** Famciclovir 125 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

**Note** Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)**

***5937***

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

### famciclovir 125 mg tablet, 40

8092X (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 32.82 | 34.03 | [a] APO-Famciclovir [TX] | [a] Auro-Famciclovir 125 [DO] |
| | | | | | [a] Ezovir [AF] | [a] Famciclovir AN [EA] |
| | | | | | [a] Famciclovir-GA [ED] | [a] Famvir [HX] |
| | | | | | [a] Favic 125 [RW] | |

### famciclovir 250 mg tablet, 20

2274Q (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 32.82 | 34.03 | [a] APO-Famciclovir [TX] | [a] Ezovir [AF] |
| | | | | | [a] Famciclovir AN [EA] | [a] Famciclovir-GA [ED] |
| | | | | | [a] Famciclovir Sandoz [SZ] | [a] Famvir [HX] |
| | | | | | [a] Favic 250 [RW] | |

## ▪ FAMCICLOVIR

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.
**Note** No applications for repeats will be authorised.

**Authority required (STREAMLINED)**
***5951***
Herpes zoster
**Clinical criteria:**

- The treatment must be administered within 72 hours of the onset of the rash.

**famciclovir 250 mg tablet, 21**

8002E (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 33.91 | 35.12 | [a] APO-Famciclovir [TX]<br>[a] Ezovir [AF]<br>[a] Famciclovir-GA [ED]<br>[a] Famciclovir Sandoz [SZ]<br>[a] Famlo [RA]<br>[a] Favic 250 [RW] | [a] Auro-Famciclovir 250 [DO]<br>[a] Famciclovir AN [EA]<br>[a] Famciclovir generichealth 250 [GQ]<br>[a] Famciclovir SCP 250 [CR]<br>[a] Famvir [HX] |

## ▪ FAMCICLOVIR

**Note** This drug is only effective if commenced within 72 hours of onset of rash.
**Note** Famciclovir 500 mg is not PBS-subsidised for chickenpox.
**Note** Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.
**Note** No applications for repeats will be authorised.

**Authority required (STREAMLINED)**
***5943***
Herpes zoster
**Clinical criteria:**

- Patient must be immunocompromised, **AND**
- The treatment must be administered within 72 hours of the onset of the rash.

**famciclovir 500 mg tablet, 30**

8897G (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 43.69 | 38.80 | [a] APO-Famciclovir [TX]<br>[a] Famciclovir AN [EA]<br>[a] Famvir [HX] | [a] Auro-Famciclovir 500 [DO]<br>[a] Famciclovir Sandoz [SZ]<br>[a] Favic 500 [RW] |

## ▪ FAMCICLOVIR

**Note** Famciclovir 500 mg is not PBS-subsidised for chickenpox.
**Note** Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

**Authority required (STREAMLINED)**
***5954***
Recurrent moderate to severe genital herpes
Treatment Phase: Episodic treatment or suppressive therapy
**Clinical criteria:**

- Patient must be immunocompromised.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**Authority required (STREAMLINED)**
***5947***
Recurrent moderate to severe oral or labial herpes
Treatment Phase: Episodic treatment
**Clinical criteria:**

- Patient must have HIV infection, **AND**
- Patient must have a CD4 cell count of less than 500 million per litre.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**Authority required (STREAMLINED)**
***5948***
Recurrent moderate to severe oral or labial herpes
Treatment Phase: Suppressive therapy
**Clinical criteria:**

- Patient must have HIV infection, **AND**
- Patient must have CD4 cell counts of less than 150 million per litre.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**Authority required (STREAMLINED)**

***5949***

Recurrent moderate to severe oral or labial herpes

Treatment Phase: Suppressive therapy

**Clinical criteria:**

- Patient must have HIV infection, **AND**
- Patient must present with other opportunistic infections or AIDS defining tumours.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**famciclovir 500 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8896F NP | 1 | 5 | .. | 71.95 | 38.80 | [a] APO-Famciclovir [TX]<br>[a] Ezovir [AF]<br>[a] Famciclovir-GA [ED]<br>[a] Famciclovir Sandoz [SZ]<br>[a] Favic 500 [RW] | [a] Auro-Famciclovir 500 [DO]<br>[a] Famciclovir AN [EA]<br>[a] Famciclovir generichealth 500 [GQ]<br>[a] Famvir [HX] |

## ▪ RIBAVIRIN

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

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

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**Population criteria:**

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**ribavirin 400 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10647J NP | 1 | 2 | .. | 161.62 | 38.80 | Ibavyr [IX] |

**ribavirin 200 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10937P NP | 1 | 2 | .. | 86.35 | 38.80 | Ibavyr [IX] |

**ribavirin 600 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10665H NP | 1 | 2 | .. | 238.48 | 38.80 | Ibavyr [IX] |

## ▪ RIBAVIRIN

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

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

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**Population criteria:**

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**ribavirin 400 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10673R NP | 1 | 5 | .. | 161.62 | 38.80 | Ibavyr [IX] |

**ribavirin 200 mg tablet, 28**

| 10928E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 86.35 | 38.80 | Ibavyr [IX] |

**ribavirin 600 mg tablet, 28**

| 10666J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 238.48 | 38.80 | Ibavyr [IX] |

## ▪ VALACICLOVIR

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)**

***5940***

Recurrent moderate to severe genital herpes

Treatment Phase: Suppressive therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**valaciclovir 500 mg tablet, 30**

| 5480K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 25.35 | 26.56 | [a] APO-Valaciclovir [TX] | [a] Chem mart Valaciclovir [CH] |
| | | | | | | [a] Shilova 500 [DO] | [a] Terry White Chemists Valaciclovir [TW] |
| | | | | | | [a] Vaclovir [AF] | [a] Valaciclovir Actavis [ED] |
| | | | | | | [a] Valaciclovir AN [EA] | [a] Valaciclovir generichealth [GQ] |
| | | | | | | [a] Valaciclovir RBX [RA] | [a] Valaciclovir SZ [HX] |
| | | | | | | [a] Valacor 500 [CR] | [a] Zelitrex [RF] |
| | | | [B]2.26 | 27.61 | 26.56 | [a] Valtrex [RW] | |

## ▪ VALACICLOVIR

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)**

***5961***

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**valaciclovir 500 mg tablet, 30**

| 8134D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 25.35 | 26.56 | [a] APO-Valaciclovir [TX] | [a] Chem mart Valaciclovir [CH] |
| | | | | | | [a] Shilova 500 [DO] | [a] Terry White Chemists Valaciclovir [TW] |
| | | | | | | [a] Vaclovir [AF] | [a] Valaciclovir Actavis [ED] |
| | | | | | | [a] Valaciclovir AN [EA] | [a] Valaciclovir generichealth [GQ] |
| | | | | | | [a] Valaciclovir RBX [RA] | [a] Valaciclovir Sandoz [SZ] |
| | | | | | | [a] Valaciclovir SZ [HX] | [a] Valacor 500 [CR] |
| | | | | | | [a] Zelitrex [RF] | |
| | | | [B]2.26 | 27.61 | 26.56 | [a] Valtrex [RW] | |

## ▪ VALACICLOVIR

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

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

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

**Authority required (STREAMLINED)**

***5960***

Initial moderate to severe genital herpes

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**valaciclovir 500 mg tablet, 10**

| 8133C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *20.59 | 21.80 | [a] APO-Valaciclovir [TX] | [a] Vaclovir [AF] |
| | | | | | | [a] Valaciclovir Actavis [ED] | [a] Valaciclovir AN [EA] |
| | | | | | | [a] Valaciclovir Sandoz [SZ] | [a] Zelitrex [RF] |
| | | | [B]2.26 | *22.85 | 21.80 | [a] Valtrex [RW] | |

## ▪ VALACICLOVIR

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.
**Note** No applications for repeats will be authorised.

**Authority required (STREAMLINED)**
***5962***
Herpes zoster
**Clinical criteria:**
- The treatment must be administered within 72 hours of the onset of the rash.

**Authority required (STREAMLINED)**
***5968***
Herpes zoster ophthalmicus

**valaciclovir 500 mg tablet, 42**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8064K NP | 1 | .. | .. | 31.05 | 32.26 | [a] APO-Valaciclovir [TX] | [a] Chem mart Valaciclovir [CH] |
| | | | | | | [a] Terry White Chemists Valaciclovir [TW] | [a] Vaclovir [AF] |
| | | | | | | [a] Valaciclovir Actavis [ED] | [a] Valaciclovir AN [EA] |
| | | | | | | [a] Valaciclovir generichealth [GQ] | [a] Valaciclovir RBX [RA] |
| | | | | | | [a] Valaciclovir Sandoz [SZ] | [a] Valacor 500 [CR] |
| | | | | | | [a] Zelitrex [RF] | |
| | | | [B]2.26 | 33.31 | 32.26 | [a] Valtrex [RW] | |

*Other antivirals*

## ▪ DACLATASVIR

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

**Authority required**
Chronic hepatitis C infection
**Clinical criteria:**
- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**daclatasvir 60 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10642D NP | 1 | 2 | .. | 7816.19 | 38.80 | Daklinza [BQ] |

**daclatasvir 30 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10645G NP | 1 | 2 | .. | 7816.19 | 38.80 | Daklinza [BQ] |

## ▪ DACLATASVIR

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

**Authority required**
Chronic hepatitis C infection
**Clinical criteria:**
- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**daclatasvir 60 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10659B NP | 1 | 5 | .. | 7816.19 | 38.80 | Daklinza [BQ] |

**daclatasvir 30 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10671P NP | 1 | 5 | .. | 7816.19 | 38.80 | Daklinza [BQ] |

## ▪ GRAZOPREVIR + ELBASVIR

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

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

**grazoprevir 100 mg + elbasvir 50 mg tablet, 28**

| 11011M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 3 | .. | 21149.52 | 38.80 | Zepatier [MK] |

## ▪ GRAZOPREVIR + ELBASVIR

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**grazoprevir 100 mg + elbasvir 50 mg tablet, 28**

| 11021C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 21149.52 | 38.80 | Zepatier [MK] |

## ▪ LEDIPASVIR + SOFOSBUVIR

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28**

| 10628J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 22216.19 | 38.80 | Harvoni [GI] |

## ▪ LEDIPASVIR + SOFOSBUVIR

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 8 weeks.

**ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28**

| 10668L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 22216.19 | 38.80 | Harvoni [GI] |

## ▪ LEDIPASVIR + SOFOSBUVIR

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10670N NP | 1 | 5 | .. | 22216.19 | 38.80 | Harvoni [GI] |

## ▪ PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56], 4 x 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10766P NP | 1 | 2 | .. | 14002.65 | 38.80 | Viekira Pak [VE] |

## ▪ PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR & RIBAVIRIN

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**Population criteria:**

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 600 mg tablet [56], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10747P NP | 1 | 5 | .. | 14002.65 | 38.80 | Viekira Pak-RBV [VE] |

**paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 200 mg tablet [168], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10771X NP | 1 | 5 | .. | 14002.65 | 38.80 | Viekira Pak-RBV [VE] |

## ▪ PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR & RIBAVIRIN

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**

- The treatment must be limited to a maximum duration of 12 weeks.

**Population criteria:**

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 600 mg tablet [56], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10769T NP | 1 | 2 | .. | 14002.65 | 38.80 | Viekira Pak-RBV [VE] |

**paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 200 mg tablet [168], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10772Y NP | 1 | 2 | .. | 14002.65 | 38.80 | Viekira Pak-RBV [VE] |

## ▪ SOFOSBUVIR

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

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**sofosbuvir 400 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10624E NP | 1 | 2 | .. | 19447.27 | 38.80 | Sovaldi [GI] |

## ▪ SOFOSBUVIR

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

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**sofosbuvir 400 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10657X NP | 1 | 5 | .. | 19447.27 | 38.80 | Sovaldi [GI] |

## ▪ SOFOSBUVIR + VELPATASVIR

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

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**sofosbuvir 400 mg + velpatasvir 100 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11147Q NP | 1 | 2 | .. | 22216.19 | 38.80 | Epclusa [GI] |

# VACCINES

## BACTERIAL VACCINES

*Pneumococcal vaccines*

### PNEUMOCOCCAL PURIFIED CAPSULAR POLYSACCHARIDES

**Restricted benefit**

Prophylaxis of pneumococcal infection

**Clinical criteria:**

- Patient must have undergone a splenectomy.

**Population criteria:**

- Patient must be aged 2 years or older.

**Restricted benefit**

Prophylaxis of pneumococcal infection

**Clinical criteria:**

- Patient must have Hodgkin's disease; OR
- Patient must have a high risk of contracting pneumococcal infections.

**pneumococcal purified capsular polysaccharides 25 microgram/0.5 mL injection, 0.5 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1903E NP | 1 | .. | .. | 48.85 | 38.80 | Pneumovax 23 [CS] |

**pneumococcal purified capsular polysaccharides 25 microgram/0.5 mL injection, 0.5 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10210J NP | 1 | .. | .. | 48.85 | 38.80 | Pneumovax 23 [CS] |

*Tetanus vaccines*

### DIPHTHERIA TOXOID + TETANUS TOXOID

**Note** For immunisation of adults and children aged greater than or equal to 8 years.

**diphtheria toxoid 2 international units/0.5 mL + tetanus toxoid 20 international units/0.5 mL injection, 5 x 0.5 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8783G NP | 1 | .. | .. | 70.61 | 38.80 | ADT Booster [CS] |

**diphtheria toxoid 2 Lf/0.5 mL + tetanus toxoid 2 Lf/0.5 mL injection, 10 x 0.5 mL vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10261C NP | 1 | .. | .. | 136.39 | 38.80 | MassBiologics tetanus and diphtheria toxoids adsorbed [CS] |

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

# ANTINEOPLASTIC AGENTS

## ALKYLATING AGENTS

*Nitrogen mustard analogues*

### CHLORAMBUCIL

**chlorambucil 2 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1163F | 4 | 2 | .. | *138.39 | 38.80 | Leukeran [AS] |

### CYCLOPHOSPHAMIDE

**cyclophosphamide 50 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10026Q | 1 | 2 | .. | 77.48 | 38.80 | Endoxan [BX] |

**cyclophosphamide 50 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1266P | 1 | 2 | .. | 31.64 | 32.85 | Cycloblastin [ZX] |

## ▪ MELPHALAN

**melphalan 2 mg tablet, 25**

2547C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 71.85 | 38.80 | Alkeran [AS] |

*Alkyl sulfonates*

## ▪ BUSULFAN

**busulfan 2 mg tablet, 100**

1128J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 88.31 | 38.80 | Myleran [AS] |

*Nitrosoureas*

## ▪ CARMUSTINE

**Note** Carmustine is not PBS-subsidised for use in conjunction with PBS-subsidised temozolomide.

**Restricted benefit**

Glioblastoma multiforme

**Clinical criteria:**

- The condition must be suspected or confirmed at the time of initial surgery.

**carmustine 7.7 mg implant, 8**

8898H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 16672.83 | 38.80 | Gliadel [EI] |

*Other alkylating agents*

## ▪ TEMOZOLOMIDE

**temozolomide 140 mg capsule, 5**

9362R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 169.23 | 38.80 | [a] APO-Temozolomide [TX]<br>[a] Temizole 140 [QA]<br>[a] Temolide [JU]<br>[a] Temozolomide Amneal [ED] | [a] Orion Temozolomide [ON]<br>[a] Temodal [MK]<br>[a] Temozolomide Alphapharm [AF]<br>[a] Temozolomide AN [EA] |

**temozolomide 5 mg capsule, 5**

8378Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 20.20 | 21.41 | [a] APO-Temozolomide [TX]<br>[a] Temizole 5 [QA]<br>[a] Temolide [JU]<br>[a] Temozolomide Amneal [ED] | [a] Orion Temozolomide [ON]<br>[a] Temodal [MK]<br>[a] Temozolomide Alphapharm [AF]<br>[a] Temozolomide AN [EA] |

**temozolomide 100 mg capsule, 5**

8380C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 125.76 | 38.80 | [a] APO-Temozolomide [TX]<br>[a] Temizole 100 [QA]<br>[a] Temolide [JU]<br>[a] Temozolomide Amneal [ED] | [a] Orion Temozolomide [ON]<br>[a] Temodal [MK]<br>[a] Temozolomide Alphapharm [AF]<br>[a] Temozolomide AN [EA] |

**temozolomide 180 mg capsule, 5**

2438H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 202.99 | 38.80 | [a] APO-Temozolomide [TX]<br>[a] Temodal [MK]<br>[a] Temozolomide Amneal [ED] | [a] Orion Temozolomide [ON]<br>[a] Temolide [JU] |

**temozolomide 20 mg capsule, 5**

8379B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 37.85 | 38.80 | [a] APO-Temozolomide [TX]<br>[a] Temizole 20 [QA]<br>[a] Temolide [JU]<br>[a] Temozolomide Amneal [ED] | [a] Orion Temozolomide [ON]<br>[a] Temodal [MK]<br>[a] Temozolomide Alphapharm [AF]<br>[a] Temozolomide AN [EA] |

**temozolomide 250 mg capsule, 5**

8381D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 286.79 | 38.80 | [a] APO-Temozolomide [TX] | [a] Orion Temozolomide [ON] |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | [a] Temizole 250 [QA]<br>[a] Temolide [JU]<br>[a] Temozolomide Amneal [ED] | [a] Temodal [MK]<br>[a] Temozolomide Alphapharm [AF]<br>[a] Temozolomide AN [EA] |

## ▪ TEMOZOLOMIDE

**Note** Temozolomide is not PBS-subsidised for use in conjunction with PBS-subsidised carmustine.
**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**
Glioblastoma multiforme
**Treatment criteria:**
- Patient must be undergoing concomitant radiotherapy.

### temozolomide 140 mg capsule, 5

9361Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 2 | .. | *495.82 | 38.80 | [a] APO-Temozolomide [TX]<br>[a] Temizole 140 [QA]<br>[a] Temolide [JU]<br>[a] Temozolomide Amneal [ED] | [a] Orion Temozolomide [ON]<br>[a] Temodal [MK]<br>[a] Temozolomide Alphapharm [AF]<br>[a] Temozolomide AN [EA] |

### temozolomide 5 mg capsule, 5

8819E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 2 | .. | *38.41 | 38.80 | [a] APO-Temozolomide [TX]<br>[a] Temizole 5 [QA]<br>[a] Temolide [JU]<br>[a] Temozolomide Amneal [ED] | [a] Orion Temozolomide [ON]<br>[a] Temodal [MK]<br>[a] Temozolomide Alphapharm [AF]<br>[a] Temozolomide AN [EA] |

### temozolomide 100 mg capsule, 5

8821G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 2 | .. | *360.85 | 38.80 | [a] APO-Temozolomide [TX]<br>[a] Temizole 100 [QA]<br>[a] Temolide [JU]<br>[a] Temozolomide Amneal [ED] | [a] Orion Temozolomide [ON]<br>[a] Temodal [MK]<br>[a] Temozolomide Alphapharm [AF]<br>[a] Temozolomide AN [EA] |

### temozolomide 180 mg capsule, 5

10062N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 2 | .. | *599.41 | 38.80 | [a] APO-Temozolomide [TX]<br>[a] Temodal [MK]<br>[a] Temozolomide Amneal [ED] | [a] Orion Temozolomide [ON]<br>[a] Temolide [JU] |

### temozolomide 20 mg capsule, 5

8820F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 2 | .. | *91.36 | 38.80 | [a] APO-Temozolomide [TX]<br>[a] Temizole 20 [QA]<br>[a] Temolide [JU]<br>[a] Temozolomide Amneal [ED] | [a] Orion Temozolomide [ON]<br>[a] Temodal [MK]<br>[a] Temozolomide Alphapharm [AF]<br>[a] Temozolomide AN [EA] |

## ANTIMETABOLITES

*Folic acid analogues*

## ▪ METHOTREXATE

### methotrexate 10 mg tablet, 15

2272N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 23.19 | 24.40 | Methoblastin [PF] |

### methotrexate 2.5 mg tablet, 30

1622J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 16.92 | 18.13 | Methoblastin [PF] |

### methotrexate 5 mg/2 mL injection, 5 x 2 mL vials

2396D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 28.79 | 30.00 | Hospira Pty Limited [PF] |

## ▪ METHOTREXATE

**Restricted benefit**

Patients requiring doses greater than 20 mg per week

**methotrexate 10 mg tablet, 50**

| 1623K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 51.41 | 38.80 | Methoblastin [PF] |

## ▪ METHOTREXATE

**Note** For item codes 2395C and 1818Q, pharmaceutical benefits that have the form injection 50 mg in 2 mL are equivalent for the purposes of substitution.

**METHOTREXATE Injection 50 mg in 2 mL, 1**

| 1818Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 5 | 5 | .. | *27.95 | 29.16 | [a] Methaccord [EA] | [a] Methotrexate Accord [OD] |

**methotrexate 50 mg/2 mL injection, 5 x 2 mL vials**

| 2395C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 27.92 | 29.13 | [a] Hospira Pty Limited [PF] |

*Purine analogues*

## ▪ FLUDARABINE

**fludarabine phosphate 10 mg tablet, 20**

| 9184J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 930.60 | 38.80 | Fludara [GZ] |

## ▪ MERCAPTOPURINE

**mercaptopurine 50 mg tablet, 25**

| 1598D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | 2 | .. | *243.07 | 38.80 | Purinethol [AS] |

**mercaptopurine 20 mg/mL oral liquid, 100 mL**

| 10214N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 435.07 | 38.80 | Allmercap [LM] |

## ▪ THIOGUANINE

**thioguanine 40 mg tablet, 25**

| 1233X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 219.57 | 38.80 | Lanvis [AS] |

*Pyrimidine analogues*

## ▪ CAPECITABINE

**capecitabine 150 mg tablet, 60**

| 8361C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 27.29 | 28.50 | [a] Capecitabine AN [EA]<br>[a] Capecitabine MYX [OC]<br>[a] Xelocitabine [JU] | [a] Capecitabine-DRLA [RZ]<br>[a] Xelabine [QA] |

**capecitabine 500 mg tablet, 120**

| 8362D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 111.51 | 38.80 | [a] Capecitabine Alphapharm [AF]<br>[a] Capecitabine Apotex [TX]<br>[a] Capecitabine MYX [OC]<br>[a] Xelabine [QA] | [a] Capecitabine AN [EA]<br>[a] Capecitabine-DRLA [RZ]<br>[a] Capecitabine Sandoz [SZ]<br>[a] Xelocitabine [JU] |
| | | | [B]5.04 | 116.55 | 38.80 | [a] Xeloda [RO] | |

# PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

*Vinca alkaloids and analogues*

## ▪ VINORELBINE

**Authority required**

Advanced breast cancer

**Clinical criteria:**

- Patient must have failed standard prior therapy, which includes an anthracycline.

**Authority required**

Locally advanced or metastatic non-small cell lung cancer

**vinorelbine 30 mg capsule, 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9010F | 16 | 2 | .. | *1878.83 | 38.80 | Navelbine [FB] |

**vinorelbine 20 mg capsule, 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9009E | 20 | 2 | .. | *1570.15 | 38.80 | Navelbine [FB] |

*Podophyllotoxin derivatives*

## ▪ ETOPOSIDE

**etoposide 50 mg capsule, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1396L | 1 | .. | .. | 440.03 | 38.80 | Vepesid [BQ] |

**etoposide 100 mg capsule, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1389D | 1 | .. | .. | 383.92 | 38.80 | Vepesid [BQ] |

# CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

*Anthracyclines and related substances*

## ▪ IDARUBICIN

**Restricted benefit**

Acute myelogenous leukaemia (AML)

**idarubicin hydrochloride 10 mg capsule, 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2448W | 3 | .. | .. | *490.51 | 38.80 | Zavedos [PF] |

**idarubicin hydrochloride 5 mg capsule, 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2446R | 3 | .. | .. | *306.61 | 38.80 | Zavedos [PF] |

# OTHER ANTINEOPLASTIC AGENTS

*Monoclonal antibodies*

## ▪ RITUXIMAB

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

**Authority required (STREAMLINED)**

***6011***

Relapsed or refractory Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Maintenance therapy

**Clinical criteria:**

- The treatment must be maintenance therapy, **AND**
- Patient must have demonstrated a partial or complete response to re-induction treatment received immediately prior to this current Authority application, **AND**
- Patient must not receive more than 8 cycles or 2 years duration of treatment, whichever comes first, under this restriction.

**rituximab 1.4 g/11.7 mL injection, 11.7 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10709P | 1 | 7 | .. | 2853.30 | 38.80 | Mabthera SC [RO] |

## ▪ RITUXIMAB

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

**Authority required (STREAMLINED)**

***5998***

Relapsed or refractory low-grade B-cell non-Hodgkin's lymphoma

Treatment Phase: Re-induction treatment

**Clinical criteria:**

- The treatment must be for re-induction treatment purposes only, **AND**
- The condition must have relapsed or be refractory to treatment, **AND**

- Patient must not receive more than 4 doses of rituximab in total, including intravenous and subcutaneous injections, and no more than 3 doses of subcutaneous rituximab under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 4 doses in total.

**Authority required (STREAMLINED)**

***6039***

Relapsed or refractory follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Re-induction treatment

**Clinical criteria:**

- The treatment must be for re-induction treatment purposes only, **AND**
- The condition must have relapsed or be refractory to treatment, **AND**
- Patient must not receive more than 4 doses of rituximab in total, including intravenous and subcutaneous injections, and no more than 3 doses of subcutaneous rituximab under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 4 doses in total.

**rituximab 1.4 g/11.7 mL injection, 11.7 mL vial**

10703H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 2853.30 | 38.80 | Mabthera SC [RO] |

## ▪ RITUXIMAB

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

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

**Authority required (STREAMLINED)**

***6161***

Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Maintenance therapy

**Clinical criteria:**

- Patient must have demonstrated a partial or complete response to induction treatment with either R-CHOP or R-CVP regimens for previously untreated follicular B-cell Non-Hodgkin's lymphoma, received immediately prior to this current Authority application, **AND**
- Patient must not have received bendamustine induction therapy, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not receive more than 12 doses or 2 years duration of treatment, whichever comes first, under this restriction.

**rituximab 1.4 g/11.7 mL injection, 11.7 mL vial**

10742J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 11 | .. | 2853.30 | 38.80 | Mabthera SC [RO] |

## ▪ RITUXIMAB

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

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

**Authority required (STREAMLINED)**

***6309***

Previously untreated aggressive CD20 positive non-Hodgkin's lymphoma

Treatment Phase: Induction treatment

**Clinical criteria:**

- The treatment must be in combination with PBS-subsidised chemotherapy, **AND**
- The condition must be previously untreated, **AND**
- The treatment must be for induction treatment purposes only, **AND**
- Patient must not receive more than the number of cycles of treatment recommended by standard guidelines for the partner chemotherapy under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 8 doses in total.

**Authority required (STREAMLINED)**

***6162***

Previously untreated symptomatic indolent CD20 positive non-Hodgkin's lymphoma in combination with chemotherapy

Treatment Phase: Induction treatment

**Clinical criteria:**

- The treatment must be in combination with PBS-subsidised chemotherapy, **AND**
- The condition must be previously untreated, **AND**
- The condition must be symptomatic, **AND**
- The treatment must be for induction treatment purposes only, **AND**
- Patient must not receive more than the number of cycles of treatment recommended by standard guidelines for the partner chemotherapy under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 8 doses in total.

**rituximab 1.4 g/11.7 mL injection, 11.7 mL vial**

10719E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 6 | .. | 2853.30 | 38.80 | Mabthera SC [RO] |

## ▪ TRASTUZUMAB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Locally advanced HER2 positive breast cancer

Treatment Phase: Continuing treatment (3 weekly regimen)

**Clinical criteria:**

- Patient must have previously received treatment with PBS-subsidised trastuzumab, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

Where a patient has a break in trastuzumab therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose.

**Authority required**

Early HER2 positive breast cancer

Treatment Phase: Continuing treatment (3 weekly regimen)

**Clinical criteria:**

- Patient must have previously received treatment with PBS-subsidised trastuzumab, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

Where a patient has a break in trastuzumab therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose.

**trastuzumab 600 mg/5 mL injection, 5 mL vial**

10682F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 2945.37 | 38.80 | Herceptin SC [RO] |

## ▪ TRASTUZUMAB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Locally advanced HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

**Clinical criteria:**

- Patient must commence treatment concurrently with neoadjuvant chemotherapy, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

HER2 positivity must be demonstrated by in situ hybridisation (ISH).

Authority applications for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Early Breast Cancer - PBS Supporting Information Form which includes:

(i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and

(ii) a copy of the signed patient acknowledgement form.

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

**Authority required**

Early HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

**Clinical criteria:**

- Patient must commence treatment concurrently with adjuvant chemotherapy, **AND**
- Patient must have undergone surgery, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

HER2 positivity must be demonstrated by in situ hybridisation (ISH).

Authority applications for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Early Breast Cancer - PBS Supporting Information Form which includes:

(i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and

(ii) a copy of the signed patient acknowledgement form.

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

**trastuzumab 600 mg/5 mL injection, 5 mL vial**

10721G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 2945.37 | 38.80 | Herceptin SC [RO] |

## ▪ TRASTUZUMAB

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

**Authority required**

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, **AND**
- The treatment must not be in combination with nab-paclitaxel, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Authority applications for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Late stage metastatic breast cancer Initial PBS authority application form which includes a copy of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH) and tick a box to state the patient has Stage IV disease.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

**trastuzumab 600 mg/5 mL injection, 5 mL vial**

10798H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 2945.37 | 38.80 | Herceptin SC [RO] |

## ▪ TRASTUZUMAB

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will be authorised.

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Where a patient has a break in trastuzumab therapy of more than 1 week from when the last dose was due, authority approval will be granted for a new loading dose.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

**trastuzumab 600 mg/5 mL injection, 5 mL vial**

10803N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 2945.37 | 38.80 | Herceptin SC [RO] |

## ▪ TRASTUZUMAB

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will be authorised.

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

**Note** Special Pricing Arrangements apply.

**Authority required**

HER2 positive breast cancer

Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition before 1 July 2015, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

**trastuzumab 600 mg/5 mL injection, 5 mL vial**

10825R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 2945.37 | 38.80 | Herceptin SC [RO] |

*Protein kinase inhibitors*

## ▪ AXITINIB

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**axitinib 5 mg tablet, 28**

10556N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *5189.53 | 38.80 | Inlyta [PF] |

**axitinib 1 mg tablet, 28**

10539Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *1120.45 | 38.80 | Inlyta [PF] |

## ▪ AXITINIB

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have progressive disease according to the Response Evaluation Criteria In Solid Tumours (RECIST) following first-line treatment with a tyrosine kinase inhibitor, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised treatment with this drug.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment.

**axitinib 5 mg tablet, 28**

| 10540R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 2 | .. | *5189.53 | 38.80 | Inlyta [PF] |

**axitinib 1 mg tablet, 28**

| 10572K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 2 | .. | *1120.45 | 38.80 | Inlyta [PF] |

## ▪ CERITINIB

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less.

**Population criteria:**

- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 February 2017, **AND**
- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not have progressive disease.

**Population criteria:**

- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

**ceritinib 150 mg capsule, 3 x 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11056X | 1 | 1 | .. | 7277.82 | 38.80 | Zykadia [NV] |

## ▪ COBIMETINIB

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

**Authority required (STREAMLINED)**

***6839***

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be receiving PBS subsidised vemurafenib concomitantly for this condition, **AND**
- Patient must not have progressive disease when treated with a BRAF inhibitor.

**cobimetinib 20 mg tablet, 63**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11074W | 1 | 3 | .. | 8187.55 | 38.80 | Cotellic [RO] |

## ▪ COBIMETINIB

**Note** A patient who has had progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***6803***

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must be receiving PBS-subsidised vemurafenib concomitantly for this condition, **AND**
- Patient must have stable or responding disease.

**cobimetinib 20 mg tablet, 63**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11075X | 1 | 5 | .. | 8187.55 | 38.80 | Cotellic [RO] |

## ▪ CRIZOTINIB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less.

**Population criteria:**

- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed ALK-Positive Non-Small-Cell Lung Cancer Authority Application - Supporting Information Form, which includes details of ALK gene rearrangement in tumour material by FISH testing.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have progressive disease.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**crizotinib 250 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10322G | 1 | 1 | .. | 7277.82 | 38.80 | Xalkori [PF] |

**crizotinib 200 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10323H | 1 | 1 | .. | 7277.82 | 38.80 | Xalkori [PF] |

## ▪ DABRAFENIB

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***6044***

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must not have been treated previously with PBS subsidised therapy; OR
- Patient must have developed intolerance to another BRAF inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

**dabrafenib 50 mg capsule, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2963Y | 1 | 3 | .. | 5890.97 | 38.80 | Tafinlar [NV] |

**dabrafenib 75 mg capsule, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2846T | 1 | 3 | .. | 8761.69 | 38.80 | Tafinlar [NV] |

## ▪ DABRAFENIB

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***6013***

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have stable or responding disease.

**dabrafenib 50 mg capsule, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2954L | 1 | 5 | .. | 5890.97 | 38.80 | Tafinlar [NV] |

**dabrafenib 75 mg capsule, 120**

| 10003L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 8761.69 | 38.80 | Tafinlar [NV] |

## ▪ DASATINIB

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.
Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.
1. Initial First-line treatment From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond
2. Continuing First-line treatment
Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.
First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.
Second and subsequent authority applications for continuing therapy may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.
3. Authority approval requirements.Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib:For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesilate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be a primary diagnosis, **AND**
- The condition must be in the chronic phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase, **AND**
- The treatment must be for first line therapy for this condition, **AND**
- Patient must not have previously experienced a failure to respond to the PBS-subsidised first line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of dasatinib of 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to dasatinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form; and

(3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and

(4) a signed patient acknowledgement form

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: First continuing treatment

**Clinical criteria:**

- The condition must be in the chronic phase, **AND**
- Patient must have received initial PBS-subsidised first line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with imatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- Patient must have demonstrated a major cytogenic response; OR
- Patient must have demonstrated a peripheral blood level of BCR-ABL of less than 1%, **AND**
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

First continuing applications for authorisation must be in writing and must include:(1) a completed authority prescription form; and(2) demonstration of continued response to treatment as evidenced by either:(a) a major cytogenetic response [see Note explaining requirements]; or(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements].Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided.

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- The condition must be in the chronic phase, **AND**
- Patient must have received the First continuing PBS-subsidised treatment with this drug as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with imatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- Patient must have maintained a major cytogenic response; OR
- Patient must have maintained a peripheral blood level of BCR-ABL of less than 1%, **AND**
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Subsequent authority applications for continuing therapy with this drug may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**dasatinib 20 mg tablet, 60**

| 1354G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 2951.16 | 38.80 | Sprycel [BQ] |

**dasatinib 70 mg tablet, 60**

| 1415L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 5862.66 | 38.80 | Sprycel [BQ] |

**dasatinib 100 mg tablet, 30**

| 1416M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 4764.09 | 38.80 | Sprycel [BQ] |

**dasatinib 50 mg tablet, 60**

| 1381Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 4764.09 | 38.80 | Sprycel [BQ] |

## ▪ DASATINIB

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib. Imatinib mesilate is not approved for use in second or third line treatment.Patients are eligible for PBS-subsidised treatment with only one of dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not

failed prior PBS-subsidised treatment with that agent.Nilotinib is not approved for patients in blast crisis.1. Initial second line treatmentFrom 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy.During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.2. Initial third line treatmentThird-line treatment with a TKI can only be approved when imatinib is used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent.From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib providing the patient did not fail that drug as first or second line therapy and for nilotinib the patient is not in blast crisis.3. Continuing treatment for second and third line treatmentAll continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.4. Authority approval requirements.Response criteria to initial treatment with dasatinib or nilotinib:For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).5. Definitions of response.A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.6. Definitions of loss of response.Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not have failed PBS-subsidised first line treatment with this drug for this condition, **AND**
- Patient must have failed an adequate trial of PBS-subsidised first line treatment with imatinib for this condition; OR
- Patient must have failed an adequate trial of PBS-subsidised first line treatment with nilotinib for this condition; OR
- Patient must have experienced intolerance, not a failure of response, to PBS-subsidised second line treatment with nilotinib for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Failure of an adequate trial of imatinib or nilotinib is defined as:(i) Lack of response to initial imatinib or nilotinib therapy, defined as either:- failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or nilotinib for patients initially treated in chronic phase; or- failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or nilotinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or- failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or nilotinib; OR(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or nilotinib therapy; OR(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or nilotinib therapy; OR(iv) Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or nilotinib for any phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or(3) Peripheral basophils greater than or equal to 20%; or(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); ORBlast crisis is defined as either:(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or(2) Extramedullary involvement other than spleen and liver; OR(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils

or platelets) during first-line imatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:(a) a completed authority prescription form; and(b) a completed Chronic Myeloid Leukaemia - Second and Third Line - Supporting Information Form; and(c) a signed patient acknowledgement; and(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report needs to be provided); and(e) where there has been a loss of response to imatinib or nilotinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received initial PBS- subsidised second line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second line treatment with nilotinib for this condition, **AND**
- Patient must have demonstrated a major cytogenetic response in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for authorisation must be in writing and must include:(1) a completed authority prescription form; and(2) a completed Chronic Myeloid Leukaemia - Second and Third Line - Application Form for continuing treatment; and (3) demonstration of continued response to treatment as evidenced by either: (a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report need be provided; or (b) a peripheral blood level of BCR-ABL of less than 1% on the international scale on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report need be provided.

**dasatinib 20 mg tablet, 60**

2478K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 2951.16 | 38.80 | Sprycel [BQ] |

**dasatinib 70 mg tablet, 60**

2485T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 5862.66 | 38.80 | Sprycel [BQ] |

**dasatinib 100 mg tablet, 30**

9342Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 4764.09 | 38.80 | Sprycel [BQ] |

**dasatinib 50 mg tablet, 60**

2482P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 4764.09 | 38.80 | Sprycel [BQ] |

## ▪ DASATINIB

**Note** Dasatinib will only be subsidised for patients with acute lymphoblastic leukaemia who are not receiving concomitant PBS-subsidised imatinib mesilate and who are not appropriate for an allogeneic haemopoietic stem cell transplant.

**Note** No applications for increased repeats will be authorised.

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have failed treatment with chemotherapy, **AND**
- Patient must have failed treatment with imatinib, **AND**
- Patient must have failed an allogeneic haemopoeitic stem cell transplantation if applicable, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Failure of treatment is defined as either:

(i) Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy and imatinib;

(ii) Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy and imatinib;

(iii) Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells expressing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Initial Treatment

**Clinical criteria:**

- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have been treated for this condition prior to 1 December 2007, **AND**
- Patient must have failed treatment with chemotherapy, **AND**
- Patient must have failed an allogeneic haemopoeitic stem cell transplantation if applicable, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells expressing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must not have progressed, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**dasatinib 20 mg tablet, 60**

9125G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 2951.16 | 38.80 | Sprycel [BQ] |

**dasatinib 70 mg tablet, 60**

| 9127J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 5862.66 | 38.80 | Sprycel [BQ] |

**dasatinib 100 mg tablet, 30**

| 9343R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 4764.09 | 38.80 | Sprycel [BQ] |

**dasatinib 50 mg tablet, 60**

| 9126H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 4764.09 | 38.80 | Sprycel [BQ] |

## ▪ ERLOTINIB

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously been issued with an authority prescription for this drug prior to 1 August 2014, **AND**
- Patient must not have progressive disease.

**Population criteria:**

- Patient must have a wild type epidermal growth factor receptor (EGFR) gene; OR
- Patient must have an epidermal growth factor receptor (EGFR) gene of unknown type.

**erlotinib 100 mg tablet, 30**

| 10019H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 1173.53 | 38.80 | Tarceva [RO] |

**erlotinib 25 mg tablet, 30**

| 10028T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 329.57 | 38.80 | Tarceva [RO] |

**erlotinib 150 mg tablet, 30**

| 10025P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 1433.50 | 38.80 | Tarceva [RO] |

## ▪ ERLOTINIB

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

**Population criteria:**

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have progressive disease.

**Population criteria:**

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

**erlotinib 100 mg tablet, 30**

| 10020J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 1173.53 | 38.80 | Tarceva [RO] |

**erlotinib 25 mg tablet, 30**

| 10022L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 329.57 | 38.80 | Tarceva [RO] |

**erlotinib 150 mg tablet, 30**

| 10014C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 1433.50 | 38.80 | Tarceva [RO] |

## ▪ EVEROLIMUS

**Note** Special Pricing Arrangements apply.

**Authority required**

Tuberous sclerosis complex (TSC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not be a candidate for curative surgical resection.

**Authority required**

Tuberous sclerosis complex (TSC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been treated with PBS-subsidised everolimus for this condition, **AND**
- Patient must have demonstrated a response to prior treatment.

**everolimus 2.5 mg tablet, 30**

| 2818H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 1404.57 | 38.80 | Afinitor [NV] |

## ▪ EVEROLIMUS

**Note** Special Pricing Arrangements apply.

**Authority required**

Tuberous sclerosis complex (TSC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not be a candidate for curative surgical resection.

**Authority required**

Tuberous sclerosis complex (TSC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been treated with PBS-subsidised everolimus for this condition, **AND**
- Patient must have demonstrated a response to prior treatment.

**Authority required**

Metastatic (Stage IV) breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must have acquired endocrine resistance as demonstrated by initial response and then recurrence or progression of disease after treatment with letrozole or anastrozole, **AND**
- The treatment must be in combination with exemestane.

**Population criteria:**

- Patient must not be pre-menopausal.

**Note** Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

**everolimus 5 mg tablet, 30**

| 2819J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 2714.52 | 38.80 | Afinitor [NV] |

**everolimus 10 mg tablet, 30**

| 2985D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 5279.52 | 38.80 | Afinitor [NV] |

## ▪ EVEROLIMUS

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

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

**Authority required**

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have disease progression, **AND**
- The treatment must be as monotherapy.

Patients who have progressive disease with this drug are no longer eligible for PBS-subsidised treatment with this drug.

**everolimus 5 mg tablet, 30**

| 10131F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 2714.52 | 38.80 | Afinitor [NV] |

**everolimus 10 mg tablet, 30**

| 10135K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 5279.52 | 38.80 | Afinitor [NV] |

## ▪ EVEROLIMUS

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

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have progressive disease according to the Response Evaluation Criteria In Solid Tumours (RECIST) following first-line treatment with a tyrosine kinase inhibitor, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.

Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

**Authority required**

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be symptomatic (despite somatostatin analogues); OR
- Patient must have disease progression, **AND**
- The treatment must be as monotherapy.

Disease progression must be documented in the patient's medical records.

Patients who have developed progressive disease on sunitinib are not eligible to receive PBS-subsidised everolimus.

Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.

**everolimus 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10133H | 1 | 2 | .. | 2714.52 | 38.80 | Afinitor [NV] |

**everolimus 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10132G | 1 | 2 | .. | 5279.52 | 38.80 | Afinitor [NV] |

## ▪ GEFITINIB

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

**Population criteria:**

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have progressive disease.

**gefitinib 250 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8769M | 1 | 3 | .. | 1433.50 | 38.80 | Iressa [AP] |

## ▪ IMATINIB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** No applications for increased repeats will be authorised.

**Authority required**

Malignant gastrointestinal stromal tumour

Treatment Phase: Initial Treatment

**Clinical criteria:**

- The condition must be metastatic; OR
- The condition must be unresectable, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must be commenced at a dose not exceeding 400 mg per day, **AND**

- The treatment must not exceed 3 months under this restriction.

Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Imatinib Mesilate PBS Authority Application for Use in the Treatment of Metastatic or Unresectable Gastrointestinal Stromal Tumour - Supporting Information Form which includes the following:

(i) a copy of a pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining; and

(ii) a copy of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease; and

(iii) where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence in support of that claim must be provided

**Authority required**

Malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be metastatic; OR
- The condition must be unresectable, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given at a dose not exceeding 600 mg per day.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

Applications for continuing treatment may be made by telephone

**Note** For the following diseases, written authority is required at initiation and for continuation:
Dermatofibrosarcoma protuberans;
Hypereosinophilic syndrome;
Chronic eosinophilic leukaemia;
Myelodysplastic or myeloproliferative disorder;
Aggressive systemic mastocytosis with eosinophilia.

**imatinib 400 mg tablet, 30**

9112N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 2486.52 | 38.80 | Glivec [AF] |

**imatinib 100 mg tablet, 60**

9111M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 1286.58 | 38.80 | Glivec [AF] |

## ▪ IMATINIB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** No applications for increased repeats will be authorised.

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Authority required**

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by standard karyotyping; OR
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by fluorescence in situ hybridization (FISH); OR
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by PDGFRB fusion gene transcript, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with cytarabine; OR
- Patient must have previously failed an adequate trial of conventional therapy with etoposide; OR
- Patient must have previously failed an adequate trial of conventional therapy with hydroxyurea, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement; and

(d) a copy of the bone marrow biopsy report which demonstrates the presence of a myelodysplastic or myeloproliferative disorder; and

(e) details of the prior therapy trialled and the response; and

(f) a signed patient acknowledgement

**Authority required**

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be PDGFRB fusion gene-positive, **AND**
- Patient must must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the full blood examination report which demonstrates a complete haematological response; and

(d) a statement that the disease has not progressed on imatinib therapy

**imatinib 400 mg tablet, 30**

| 9177B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 2486.52 | 38.80 | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] | [a] IMATINIB RBX [RA] |

**imatinib 100 mg tablet, 60**

| 9176Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 1286.58 | 38.80 | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] | [a] IMATINIB RBX [RA] |

**imatinib 400 mg capsule, 30**

| 10939R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 2486.52 | 38.80 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB AN [EA]<br>[a] IMATINIB-DRLA [RZ] | [a] Glivanib [JU]<br>[a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] |

**imatinib 100 mg capsule, 60**

| 10918P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 1286.58 | 38.80 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB AN [EA]<br>[a] IMATINIB-DRLA [RZ] | [a] Glivanib [JU]<br>[a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] |

## ▪ IMATINIB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** No applications for increased repeats will be authorised.

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Authority required**

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene; and

(d) a copy of the full blood examination report confirming the presence of hypereosinophilic syndrome or chronic eosinophilic leukaemia; and

(e) details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and

(f) a signed patient acknowledgement

**Authority required**

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count; and

(d) a statement that the disease has not progressed on imatinib therapy

**imatinib 400 mg tablet, 30**

9175X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 2486.52 | 38.80 | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] | [a] IMATINIB RBX [RA] |

**imatinib 100 mg tablet, 60**

9174W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 1286.58 | 38.80 | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] | [a] IMATINIB RBX [RA] |

**imatinib 400 mg capsule, 30**

10925B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 2486.52 | 38.80 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB AN [EA]<br>[a] IMATINIB-DRLA [RZ] | [a] Glivanib [JU]<br>[a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] |

**imatinib 100 mg capsule, 60**

10941W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 1286.58 | 38.80 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB AN [EA]<br>[a] IMATINIB-DRLA [RZ] | [a] Glivanib [JU]<br>[a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] |

## ▪ IMATINIB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** No applications for increased repeats will be authorised.

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Authority required**

Dermatofibrosarcoma protuberans

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

(1) Where the application for authority to prescribe is being sought on the basis of unresectable tumour, written evidence in support of that claim must be provided; and

(2) Where the application for authority to prescribe is being sought on the basis of locally recurrent disease, the site of the local recurrence must be specified; and

(3) Where the application for authority to prescribe is being sought on the basis of metastatic disease, the site(s) of metastatic disease must be provided.

Applications for authorisation for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a signed patient acknowledgement

**Authority required**

Dermatofibrosarcoma protuberans

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to the PBS-subsidised treatment, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a statement that the disease has not progressed on imatinib therapy

**imatinib 400 mg tablet, 30**

| 9173T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 2486.52 | 38.80 | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] | [a] IMATINIB RBX [RA] |

**imatinib 100 mg tablet, 60**

| 9172R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 1286.58 | 38.80 | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] | [a] IMATINIB RBX [RA] |

**imatinib 400 mg capsule, 30**

| 10933K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 2486.52 | 38.80 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB AN [EA]<br>[a] IMATINIB-DRLA [RZ] | [a] Glivanib [JU]<br>[a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] |

**imatinib 100 mg capsule, 60**

| 10942X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 1286.58 | 38.80 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB AN [EA]<br>[a] IMATINIB-DRLA [RZ] | [a] Glivanib [JU]<br>[a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] |

## ▪ IMATINIB

**Authority required**

Gastrointestinal stromal tumour

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**

- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy).

Applications for authorisation of initial treatment must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in Adjuvant Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form which includes the following:

(i) a copy of a pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining; and

(ii) a copy of the pathology report must include the size and mitotic rate of the tumour, and the date of tumour resection must be documented, which must not be more than 3 months prior to the date of this application.

High risk of recurrence is defined as:

Primary GIST greater than 5 cm with a mitotic count of greater than 5/50 high power fields (HPF); or

Primary GIST greater than 10 cm with any mitotic rate; or

Primary GIST with a mitotic count of greater than 10/50 HPF.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Any queries concerning patients who are enrolled on the Imatinib Compassionate Program may be directed to the Department of Human Services on 1800 700 270**.**

**Authority required**

Gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy), **AND**
- Patient must have previously been issued with an authority prescription for imatinib for adjuvant treatment following complete resection of primary GIST.

Applications for continuing therapy may be made by telephone.

**Note** Authority approval for continuing treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**imatinib 400 mg tablet, 30**

5444M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 2486.52 | 38.80 | Glivec [AF] |

**imatinib 100 mg tablet, 60**

5443L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1286.58 | 38.80 | Glivec [AF] |

## ▪ IMATINIB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Authority required**

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with corticosteroids; OR
- Patient must have previously failed an adequate trial of conventional therapy with hydroxyurea, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene; and

(d) a copy of the bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a copy of the full blood examination report demonstrating eosinophilia; and

(e) details of symptomatic organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and

(f) details of prior treatment trialled and the response; and

(g) a signed patient acknowledgement

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

**Authority required**

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene, **AND**
- Patient must must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the full blood examination report which demonstrates a complete haematological response; and

(d) a statement that the disease has not progressed on imatinib therapy

**Note** No applications for increased repeats will be authorised.

**imatinib 400 mg tablet, 30**

| 9179D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 2486.52 | 38.80 | [a] Glivec [AF] | [a] IMATINIB RBX [RA] |

**imatinib 100 mg tablet, 60**

| 9178C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 1286.58 | 38.80 | [a] Glivec [AF] | [a] IMATINIB RBX [RA] |

**imatinib 400 mg capsule, 30**

| 10921T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 2486.52 | 38.80 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB AN [EA]<br>[a] IMATINIB-DRLA [RZ] | [a] Glivanib [JU]<br>[a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] |

**imatinib 100 mg capsule, 60**

| 10940T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 1286.58 | 38.80 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB AN [EA]<br>[a] IMATINIB-DRLA [RZ] | [a] Glivanib [JU]<br>[a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] |

## ▪ IMATINIB

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond

2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive

continuing therapy.
First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.
Second and subsequent authority applications for continuing therapy may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.
3. Authority approval requirements.Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib:For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesilate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the chronic phase of chronic myeloid leukaemia, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase, **AND**
- The treatment must be for first line therapy for this condition, **AND**
- Patient must not have previously experienced a failure to respond to the PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for authorisation must be in writing and must include:(1) a completed authority prescription form; and(2) a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form; and(3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and(4) a signed patient acknowledgement form

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of imatinib mesilate of 400 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to imatinib mesilate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: First Continuing

**Clinical criteria:**

- The condition must be in the chronic phase of chronic myeloid leukaemia, **AND**
- Patient must have received initial PBS-subsidised treatment with this drug as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with dasatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- Patient must have demonstrated a major cytogenic response; OR
- Patient must have demonstrated a peripheral blood level of BCR-ABL of less than 1%, **AND**
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

First continuing applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a response to treatment as evidenced by either:

(a) a major cytogenetic response [see Note explaining requirements]; or

(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements].

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Subsequent continuing

**Clinical criteria:**

- The condition must be in the chronic phase of chronic myeloid leukaemia, **AND**
- Patient must have received initial continuing PBS-subsidised treatment with this drug as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with dasatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- Patient must have maintained a major cytogenic response; OR
- Patient must have maintained a peripheral blood level of BCR-ABL of less than 1%, **AND**
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Second and subsequent authority applications for continuing therapy with imatinib mesilate may be made on the telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**imatinib 400 mg tablet, 30**

9114Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 2486.52 | 38.80 | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] | [a] IMATINIB RBX [RA] |

**imatinib 100 mg tablet, 60**

9113P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 1286.58 | 38.80 | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] | [a] IMATINIB RBX [RA] |

**imatinib 400 mg capsule, 30**

10916M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 2486.52 | 38.80 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB AN [EA]<br>[a] IMATINIB-DRLA [RZ] | [a] Glivanib [JU]<br>[a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] |

**imatinib 100 mg capsule, 60**

10915L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 1286.58 | 38.80 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB AN [EA]<br>[a] IMATINIB-DRLA [RZ] | [a] Glivanib [JU]<br>[a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] |

## ▪ IMATINIB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** No applications for increased repeats will be authorised.

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

3. Peripheral basophils greater than or equal to 20%; or

4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Imatinib Mesilate PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and

(c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criteria (1), (2), (3) and (5) above, or details of the dates of assessments in the case of progressive splenomegaly

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

2. Extramedullary involvement other than spleen and liver.

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Imatinib Mesilate PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and

(c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criterion (1) above, or details of the date of assessment in the case of extramedullary involvement

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

**imatinib 400 mg tablet, 30**

9116T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 2486.52 | 38.80 | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] | [a] IMATINIB RBX [RA] |

**imatinib 100 mg tablet, 60**

9115R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 1286.58 | 38.80 | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] | [a] IMATINIB RBX [RA] |

**imatinib 400 mg capsule, 30**

10935M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 2486.52 | 38.80 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB AN [EA]<br>[a] IMATINIB-DRLA [RZ] | [a] Glivanib [JU]<br>[a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] |

**imatinib 100 mg capsule, 60**

10920R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 1286.58 | 38.80 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB AN [EA]<br>[a] IMATINIB-DRLA [RZ] | [a] Glivanib [JU]<br>[a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] |

## ▪ IMATINIB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

**Note** No applications for increased repeats will be authorised.

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be newly diagnosed, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for induction and consolidation therapy, **AND**
- The treatment must be in combination with chemotherapy.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and

(c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and

(d) a signed patient acknowledgement

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have previously received treatment with this drug for this condition under Imatinib Compassionate Program.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and

(c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and

(d) a signed patient acknowledgement

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for maintenance of first complete remission, **AND**
- The treatment must be in combination with chemotherapy.

Imatinib is available with a lifetime maximum of 24 months for continuing treatment with imatinib therapy for patients with acute lymphoblastic leukaemia reimbursed through the PBS.

**Note** Any queries concerning the arrangements to prescribe this drug beyond 24 months may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**imatinib 400 mg tablet, 30**

| 9124F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 2486.52 | 38.80 | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] | [a] IMATINIB RBX [RA] |

**imatinib 100 mg tablet, 60**

| 9123E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 1286.58 | 38.80 | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] | [a] IMATINIB RBX [RA] |

**imatinib 400 mg capsule, 30**

| 10917N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 2486.52 | 38.80 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB AN [EA]<br>[a] IMATINIB-DRLA [RZ] | [a] Glivanib [JU]<br>[a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] |

**imatinib 100 mg capsule, 60**

| 10924Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 1286.58 | 38.80 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB AN [EA]<br>[a] IMATINIB-DRLA [RZ] | [a] Glivanib [JU]<br>[a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] |

## ▪ LAPATINIB

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will be authorised.

**Authority required**

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, **AND**
- The treatment must be in combination with capecitabine, **AND**
- Patient must have received prior therapy with a taxane for at least 3 cycles; OR

- Patient must have developed intolerance to treatment with a taxane of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must have progressed following treatment with pertuzumab and trastuzumab in combination, **AND**
- The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Authority applications for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Late stage metastatic breast cancer Initial PBS authority application form which includes:

(i) a copy of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH) and tick a box to state the person has Stage IV disease;

(ii) date of last treatment with a taxane and total number of cycles;

(iii) a copy of the signed patient acknowledgement form;

(iv) dates of treatment with trastuzumab and pertuzumab; and

(v) date of demonstration of progression whilst on treatment with trastuzumab and pertuzumab.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- The treatment must be in combination with capecitabine, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

The treatment must not exceed a lifetime total of one continuous course.

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

**lapatinib 250 mg tablet, 70**

9148L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *3228.57 | 38.80 | Tykerb [NV] |

## ▪ LENVATINIB

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

**Authority required (STREAMLINED)**

***6604***

Locally advanced or metastatic differentiated thyroid cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be refractory to radioactive iodine, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have symptomatic progressive disease prior to treatment; OR
- Patient must have progressive disease at critical sites with a high risk of morbidity or mortality where local control cannot be achieved by other measures, **AND**
- Patient must have thyroid stimulating hormone adequately repressed, **AND**

- Patient must be one in whom surgery is inappropriate, **AND**
- Patient must not be a candidate for radiotherapy with curative intent, **AND**
- Patient must have a WHO performance status of 2 or less.

Radioactive iodine refractory is defined as:

- a lesion without iodine uptake on a radioactive iodine (RAI) scan; or
- having received a cumulative RAI dose of greater than or equal to 600 mCi; or
- progression within 12 months of a single RAI treatment; or
- progression after two RAI treatments administered within 12 months of each other.

**Authority required (STREAMLINED)**

***6578***

Locally advanced or metastatic differentiated thyroid cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be refractory to radioactive iodine, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST).

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

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**Authority required (STREAMLINED)**

***6577***

Locally advanced or metastatic differentiated thyroid cancer

Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- The condition must be refractory to radioactive iodine, **AND**
- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2016, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have thyroid stimulating hormone adequately repressed.

**lenvatinib 4 mg capsule, 30**

10952K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 3304.52 | 38.80 | Lenvima [EI] |

**lenvatinib 10 mg capsule, 30**

10965D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *6459.53 | 38.80 | Lenvima [EI] |

## ▪ NILOTINIB

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be a primary diagnosis, **AND**
- The condition must be in the chronic phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase, **AND**
- The treatment must be for first line therapy for this condition, **AND**
- Patient must not have previously experienced a failure to respond to the PBS-subsidised first line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.Patients should be commenced on a dose of nilotinib of 300 mg twice daily. Continuing therapy is dependent on patients demonstrating a response to nilotinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.Applications for authorisation must be in writing and must include:(1) a completed authority prescription form; and(2) a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form; and(3) a pathology cytogenetic report conducted on peripheral

blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and(4) a signed patient acknowledgement formThe following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond 2. Continuing First-line treatment -

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.

Second and subsequent authority applications for continuing therapy may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason ofintolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

3. Authority approval requirements.Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib:For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesilate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response.A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

5. Definitions of loss of response.Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: First continuing treatment

**Clinical criteria:**

- The condition must be in the chronic phase, **AND**
- Patient must have received initial PBS-subsidised first line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with imatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with dasatinib as a first line therapy for this condition, **AND**
- Patient must have demonstrated a major cytogenic response; OR
- Patient must have demonstrated a peripheral blood level of BCR-ABL of less than 1%, **AND**
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

First continuing applications for authorisation must be in writing and must include:(1) a completed authority prescription form; and(2) demonstration of continued response to treatment as evidenced by either:(a) a major cytogenetic response [see Note explaining requirements]; or(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note

explaining requirements].Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided.

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- The condition must be in the chronic phase, **AND**
- Patient must have received the First continuing PBS-subsidised treatment with this drug as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with imatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with dasatinib as a first line therapy for this condition, **AND**
- Patient must have maintained a major cytogenic response; OR
- Patient must have maintained a peripheral blood level of BCR-ABL of less than 1%, **AND**
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Subsequent authority applications for continuing therapy with this drug may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**NILOTINIB Capsule 150 mg (as hydrochloride monohydrate), 120**

1309X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 4254.95 | 38.80 | Tasigna [NV] |

## ▪ NILOTINIB

**Note** Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe this drug should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be in the chronic phase; OR
- The condition must be in the accelerated phase, **AND**
- Patient must have failed an adequate trial of PBS-subsidised first line treatment with imatinib for this condition; OR
- Patient must have failed an adequate trial of PBS-subsidised first line treatment with dasatinib for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Failure of an adequate trial of imatinib or dasatinib is defined as:(i) Lack of response to initial imatinib or dasatinib therapy, defined as either:- failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib for patients initially treated in chronic phase; or- failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or- failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib; OR(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib therapy; OR(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or dasatinib therapy; OR(iv) Development of accelerated phase in a patient previously prescribed imatinib or dasatinib for the chronic phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or(3) Peripheral basophils greater than or equal to 20%; or(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR(v) Disease progression (defined as a greater than or equal to.50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or dasatinib therapy in patients with accelerated phase chronic myeloid leukaemia, provided that blast crisis has been excluded on bone marrow biopsy.

Patients should be commenced on a dose of nilotinib of 400 mg twice daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to nilotinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:(a) a completed authority prescription form; and(b) a completed Chronic Myeloid Leukaemia - Second and Third Line - Supporting Information Form; and(c) a signed patient

acknowledgement; and(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report needs to be provided); and(e) where there has been a loss of response to imatinib or dasatinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib. Imatinib mesilate is not approved for use in second or third line treatment.Patients are eligible for PBS-subsidised treatment with only one of dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent.Nilotinib is not approved for patients in blast crisis.1. Initial second line treatmentFrom 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy.During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.2. Initial third line treatmentThird-line treatment with a TKI can only be approved when imatinib is used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent.From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib providing the patient did not fail that drug as first or second line therapy and for nilotinib the patient is not in blast crisis.3. Continuing treatment for second and third line treatmentAll continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.4. Authority approval requirements.Response criteria to initial treatment with dasatinib or nilotinib:For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).5. Definitions of response.A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.6. Definitions of loss of response.Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a major cytogenetic response to nilotinib in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% to nilotinib in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for authorisation must be in writing and must include:(1) a completed authority prescription form; and(2) a completed Chronic Myeloid Leukaemia - Second and Third Line - Application Form for continuing treatment; and(3) demonstration of continued response to treatment as evidenced by either:(a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided; or(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided

**NILOTINIB Capsule 200 mg (as hydrochloride monohydrate), 120**

9171Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 5589.01 | 38.80 | Tasigna [NV] |

## ▪ NINTEDANIB

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 1 - new patient

**Clinical criteria:**

- The condition must be diagnosed through a multidisciplinary team, **AND**
- Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months, **AND**
- Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height, **AND**
- Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7, **AND**
- Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%, **AND**
- Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition.

**Treatment criteria:**

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

Patient must have not have an acute respiratory infection at the time of FVC testing.

Applications for authorisation of initial treatment must be in writing and must include:

a) a completed authority prescription form; and

b) a completed IPF Authority Application Supporting Information Form; and

c) a signed patient acknowledgement.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 2 - change or re-commencement of treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition.

**Treatment criteria:**

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition.

**Treatment criteria:**

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 3 - Grandfathering treatment

**Treatment criteria:**

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2017, **AND**
- The condition must have been diagnosed through a multidisciplinary team, **AND**
- Patient must have had a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height at the time treatment with this drug for this condition was initiated, **AND**

- Patient must have had a forced expiratory volume in 1 second (FEV1)/FVC ratio greater than 0.7 at the time treatment with this drug for this condition was initiated, **AND**
- Patient must have had diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30% at the time treatment with this drug for this condition was initiated, **AND**
- Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition.

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

Patient must have not have an acute respiratory infection at the time of FVC testing.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

Applications for authorisation of initial treatment must be in writing and must include:

a) a completed authority prescription form; and

b) a completed IPF Authority Application Supporting Information Form; and

c) a signed patient acknowledgement.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**nintedanib 100 mg capsule, 60**

11100F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1752.64 | 38.80 | Ofev [BY] |

**nintedanib 150 mg capsule, 60**

11106M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 3387.12 | 38.80 | Ofev [BY] |

## ▪ PAZOPANIB

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

**Authority required**

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have received prior chemotherapy treatment including an anthracycline, **AND**
- Patient must not have received prior treatment with an angiogenesis inhibitor, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patient must not have any of the following conditions:
adipocytic soft tissue sarcoma;
gastrointestinal stromal tumour (GIST);
rhabdomyosarcoma other than alveolar or pleomorphic;
chondrosarcoma;
osteosarcoma;
Ewings tumour/primitive neuroectodermal tumour;
dermofibromatosis sarcoma protuberans;
inflammatory myofibroblastic sarcoma;
malignant mesothelioma;
mixed mesodermal tumour of the uterus.
The authority application must be made in writing.

**pazopanib 400 mg tablet, 60**

10041L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 4676.80 | 38.80 | Votrient [NV] |

**pazopanib 200 mg tablet, 90**

| 10042M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 3544.98 | 38.80 | Votrient [NV] |

## ▪ PAZOPANIB

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for pazopanib, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for continuing therapy may be made by telephone.

**pazopanib 400 mg tablet, 60**

| 10043N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 4676.80 | 38.80 | Votrient [NV] |

**pazopanib 200 mg tablet, 90**

| 10047T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 3544.98 | 38.80 | Votrient [NV] |

## ▪ PAZOPANIB

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for pazopanib, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- Patient must require dose adjustment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for continuing therapy may be made by telephone.

**pazopanib 400 mg tablet, 30**

| 10052C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 2413.16 | 38.80 | Votrient [NV] |

**pazopanib 200 mg tablet, 30**

| 10054E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 1248.61 | 38.80 | Votrient [NV] |

## ▪ PAZOPANIB

**Note** Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

**Note** Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for pazopanib, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- Patient must require dose adjustment, **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

**pazopanib 400 mg tablet, 30**

2201W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 2413.16 | 38.80 | Votrient [NV] |

**pazopanib 200 mg tablet, 30**

2232L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1248.61 | 38.80 | Votrient [NV] |

## ▪ PAZOPANIB

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

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

**Note** Special Pricing Arrangements apply.

**Note** Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised pazopanib.

**Note** Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must meet the Memorial Sloan Kettering Cancer Centre (MSKCC) low to intermediate risk group criteria, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

**pazopanib 400 mg tablet, 60**

2030W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 4676.80 | 38.80 | Votrient [NV] |

**pazopanib 200 mg tablet, 90**

2029T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 3544.98 | 38.80 | Votrient [NV] |

## ▪ PAZOPANIB

**Note** Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for pazopanib, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

**Note** Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have been receiving treatment with pazopanib prior to 1 October 2012, **AND**

- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

**pazopanib 400 mg tablet, 60**

| 2035D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 4676.80 | 38.80 | Votrient [NV] |

**pazopanib 200 mg tablet, 90**

| 2034C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 3544.98 | 38.80 | Votrient [NV] |

## ▪ PONATINIB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Patients are eligible for PBS-subsidised treatment with only one of imatinib, dasatinib, nilotinib or ponatinib at any one time and must not be receiving concomitant interferon alfa therapy.
1. Continuing treatment
All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:
(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and
(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.
2. Authority approval requirements.
Response criteria to initial treatment with ponatinib:
For the purposes of assessing response to PBS-subsidised treatment with ponatinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib, nilotinib or ponatinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
3. Definitions of response.
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.
A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
4. Definitions of loss of response.
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor therapy.
Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have failed an adequate trial of dasatinib; OR
- Patient must have developed intolerance to dasatinib of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have failed an adequate trial of nilotinib; OR
- Patient must have developed intolerance to nilotinib of a severity necessitating permanent treatment withdrawal; OR
- Patient must not be eligible for PBS-subsidised treatment with nilotinib because the patient has a blast crisis.

Failure of an adequate trial of dasatinib or nilotinib is defined as:

1. Lack of response to dasatinib or nilotinib therapy, defined as either:

(i) failure to achieve a haematological response after a minimum of 3 months therapy with dasatinib or nilotinib; or
(ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy with dasatinib or nilotinib as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or
(iii) failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with dasatinib or nilotinib; OR

2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing dasatinib or nilotinib therapy; OR

3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing dasatinib or nilotinib therapy; OR

4. Development of accelerated phase or blast crisis in a patient previously prescribed dasatinib or nilotinib for any phase of chronic myeloid leukaemia; OR

5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during dasatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

3. Peripheral basophils greater than or equal to 20%; or

4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

2. Extramedullary involvement other than spleen and liver.

The authority application must be made in writing and must include:

1. a completed authority prescription form;

2. a completed Chronic Myeloid Leukaemia - ponatinib Initial PBS authority application form;

3. a signed patient acknowledgement;

4. a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report, which should be within the previous 6 months, needs to be provided); and

5. where there has been a loss of response to dasatinib or nilotinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be expressing the T315I mutation, **AND**
- Patient must have failed an adequate trial of imatinib; OR
- Patient must have failed an adequate trial of dasatinib; OR
- Patient must have failed an adequate trial of nilotinib.

Failure of an adequate trial of imatinib or dasatinib or nilotinib is defined as:

1. Lack of response to imatinib or dasatinib or nilotinib therapy, defined as either:

(i) failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib or nilotinib; or

(ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib or nilotinib as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

(iii) failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib or nilotinib; OR

2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib or nilotinib therapy; OR

3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or dasatinib or nilotinib therapy; OR

4. Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or dasatinib or nilotinib for any phase of chronic myeloid leukaemia; OR

5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during imatinib or dasatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

3. Peripheral basophils greater than or equal to 20%; or

4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

2. Extramedullary involvement other than spleen and liver.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and

2. a completed Chronic Myeloid Leukaemia - ponatinib Initial PBS authority application form; and

3. a signed patient acknowledgement; and

4. a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale and evidence of the T315I mutation. (The date of the relevant pathology report(s), which should be within the previous 6 months, need(s) to be provided); and

5. where there has been a loss of response to imatinib or dasatinib or nilotinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have demonstrated either a major cytogenetic response, or less than 1% BCR-ABL level in the blood, to ponatinib within 18 months of commencement and at no greater than 12 month intervals thereafter.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and

2. a completed Chronic Myeloid Leukaemia Continuing PBS authority application Supporting information form; and

3. demonstration of continued response to treatment as evidenced by either:

(a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided; or

(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided.

**ponatinib 15 mg tablet, 60**

10520Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 5758.13 | 38.80 | Iclusig [TS] |

**ponatinib 45 mg tablet, 30**

10530F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 6477.57 | 38.80 | Iclusig [TS] |

## ▪ PONATINIB

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be expressing the T315I mutation, **AND**
- Patient must have failed treatment with chemotherapy, with or without another tyrosine kinase inhibitor, **AND**
- Patient must have failed allogeneic haemopoietic stem cell transplantation (where appropriate).

Failure of treatment is defined as either:

1. Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy, with or without another tyrosine kinase inhibitor;

2. Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy, with or without another tyrosine kinase inhibitor;

3. Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and

2. a completed Acute Lymphoblastic Leukaemia - ponatinib Initial PBS authority application form; and

3. a signed patient acknowledgement; and

4. a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript.; and evidence of the T315I mutation. The date of the relevant pathology report(s), which should be within the previous 6 months, need(s) to be provided

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have progressive disease.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**ponatinib 15 mg tablet, 60**

10523W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 5758.13 | 38.80 | Iclusig [TS] |

**ponatinib 45 mg tablet, 30**

10524X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 6477.57 | 38.80 | Iclusig [TS] |

## ▪ RUXOLITINIB

**Note** Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) OR the Dynamic International Prognostic Scoring System (DIPSS) OR the Age-Adjusted DIPSS.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No increase in the maximum quantity may be authorised for the 15 mg and 20 mg dose strengths.

**Note** Special Pricing Arrangements apply.

**Authority required**

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**Authority required**

Intermediate-1 risk myelofibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**ruxolitinib 5 mg tablet, 56**

10616R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *5149.53 | 38.80 | Jakavi [NV] |

**ruxolitinib 20 mg tablet, 56**

10617T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 5149.52 | 38.80 | Jakavi [NV] |

**ruxolitinib 15 mg tablet, 56**

| 10615Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 5149.52 | 38.80 | Jakavi [NV] |

**ruxolitinib 10 mg tablet, 56**

| 10927D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 5149.52 | 38.80 | Jakavi [NV] |

## ▪ RUXOLITINIB

**Note** Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) OR the Dynamic International Prognostic Scoring System (DIPSS) OR the Age-Adjusted DIPSS.

**Note** Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Programs
Reply Paid 9826
HOBART TAS 7001

**Note** No increase in the maximum quantity may be authorised for the 15 mg and 20 mg dose strengths.

**Note** Special Pricing Arrangements apply.

**Authority required**

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis.

**Note** The authority application must be made in writing and must include:
(1) A completed authority prescription form; and
(2) A completed Myelofibrosis Authority Application Supporting Information Form, which includes all of the following:
(a) A copy of the bone marrow biopsy report confirming diagnosis of myelofibrosis; and
(b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.

**Authority required**

Intermediate-1 risk myelofibrosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, **AND**
- Patient must have severe disease-related symptoms that are resistant, refractory or intolerant to available therapy.

**Note** The authority application must be made in writing and must include:
(1) A completed authority prescription form; and
(2) A completed Myelofibrosis Authority Application Supporting Information Form, which includes all of the following:
a) A copy of the bone marrow biopsy report confirming diagnosis of myelofibrosis;
b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS; and
c) A confirmation that the patient's disease related symptoms are resistant, refractory or intolerant to available therapy.

**ruxolitinib 5 mg tablet, 56**

| 10614P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *5149.53 | 38.80 | Jakavi [NV] |

**ruxolitinib 20 mg tablet, 56**

| 10618W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 5149.52 | 38.80 | Jakavi [NV] |

**ruxolitinib 15 mg tablet, 56**

| 10619X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 5149.52 | 38.80 | Jakavi [NV] |

**ruxolitinib 10 mg tablet, 56**

| 10913J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 5149.52 | 38.80 | Jakavi [NV] |

## ▪ SORAFENIB

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

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

**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**
Stage IV clear cell variant renal cell carcinoma (RCC)
Treatment Phase: Initial treatment
**Clinical criteria:**

- Patient must have progressive disease according to the Response Evaluation Criteria In Solid Tumours (RECIST) following first-line treatment with a tyrosine kinase inhibitor, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised treatment with this drug.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**sorafenib 200 mg tablet, 60**

| 10226F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 2 | .. | *6144.71 | 38.80 | Nexavar [BN] |

## ▪ SORAFENIB

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**
Stage IV clear cell variant renal cell carcinoma (RCC)
Treatment Phase: Continuing treatment beyond 3 months
**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**sorafenib 200 mg tablet, 60**

| 10242C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *6144.71 | 38.80 | Nexavar [BN] |

## ▪ SORAFENIB

**Note** Sorafenib is not PBS-subsidised for adjunctive treatment after resection, ablation or chemoembolization.
Sorafenib is not PBS-subsidised for maintenance therapy after disease progression.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**
***4230***
Advanced Barcelona Clinic Liver Cancer Stage C hepatocellular carcinoma
Treatment Phase: Initial
**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have Child Pugh class A.

**Authority required (STREAMLINED)**
***4234***
Advanced Barcelona Clinic Liver Cancer Stage C hepatocellular carcinoma
Treatment Phase: Continuing
**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been treated with PBS-subsidised sorafenib, **AND**
- Patient must not have progressive disease.

**sorafenib 200 mg tablet, 60**

| 9380Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 2 | .. | *6144.71 | 38.80 | Nexavar [BN] |

## ▪ SUNITINIB

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

**Authority required**

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be symptomatic (despite somatostatin analogues); OR
- Patient must have disease progression, **AND**
- The treatment must be as monotherapy.

Disease progression must be documented in the patient's medical records.

Patients who have developed progressive disease on everolimus are not eligible to receive PBS-subsidised sunitinib for this condition.

Patients who have developed intolerance to everolimus of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib.

**sunitinib 37.5 mg capsule, 28**

| 10464R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 4959.60 | 38.80 | Sutent [PF] |

**sunitinib 25 mg capsule, 28**

| 2959R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 3356.15 | 38.80 | Sutent [PF] |

**sunitinib 50 mg capsule, 28**

| 2837H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 6563.05 | 38.80 | Sutent [PF] |

**sunitinib 12.5 mg capsule, 28**

| 10004M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 1736.75 | 38.80 | Sutent [PF] |

## ▪ SUNITINIB

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

**Authority required**

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have disease progression, **AND**
- The treatment must be as monotherapy.

Patients who have progressive disease with this drug are no longer eligible for PBS-subsidised treatment with this drug.

**sunitinib 37.5 mg capsule, 28**

| 10473F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 4959.60 | 38.80 | Sutent [PF] |

**sunitinib 25 mg capsule, 28**

| 2842N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 3356.15 | 38.80 | Sutent [PF] |

**sunitinib 50 mg capsule, 28**

| 10010W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 6563.05 | 38.80 | Sutent [PF] |

**sunitinib 12.5 mg capsule, 28**

| 10009T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 1736.75 | 38.80 | Sutent [PF] |

## ▪ SUNITINIB

**Note** Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.

**Note** Patients who have developed progressive disease on pazopanib are not eligible to receive PBS-subsidised sunitinib.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for sunitinib, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

**sunitinib 37.5 mg capsule, 28**

| 10459L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 4959.60 | 38.80 | Sutent [PF] |

**sunitinib 25 mg capsule, 28**

| 9421W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 3356.15 | 38.80 | Sutent [PF] |

**sunitinib 50 mg capsule, 28**

| 9422X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 6563.05 | 38.80 | Sutent [PF] |

**sunitinib 12.5 mg capsule, 28**

| 9420T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 1736.75 | 38.80 | Sutent [PF] |

## ▪ SUNITINIB

**Note** Patients who have developed intolerance to pazopanib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib.

**Note** Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must meet the Memorial Sloan Kettering Cancer Centre (MSKCC) low to intermediate risk group criteria, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

Patients who have developed progressive disease on pazopanib are not eligible to receive PBS-subsidised sunitinib.

**sunitinib 37.5 mg capsule, 28**

| 10504W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 4959.60 | 38.80 | Sutent [PF] |

**sunitinib 25 mg capsule, 28**

| 9418Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 3356.15 | 38.80 | Sutent [PF] |

**sunitinib 50 mg capsule, 28**

| 9419R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 6563.05 | 38.80 | Sutent [PF] |

**sunitinib 12.5 mg capsule, 28**

| 9417P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 1736.75 | 38.80 | Sutent [PF] |

## ▪ SUNITINIB

**Note** Sunitinib malate is not PBS-subsidised for the treatment of patients with resectable malignant gastrointestinal stromal tumours.

**Note** Any queries concerning patients who are enrolled on the Sunitinib Compassionate Program may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Metastatic or unresectable malignant gastrointestinal stromal tumour

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have previously failed or be intolerant to imatinib mesylate.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Sunitinib Malate (Sutent) PBS Authority Application for Use in the Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form; and

(3) a signed patient acknowledgement.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

**Authority required**

Metastatic or unresectable malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- The treatment must be as monotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not have progressive disease.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.

**Note** Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS subsidised imatinib after progression on this drug

**sunitinib 37.5 mg capsule, 28**

| 10503T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 4959.60 | 38.80 | Sutent [PF] |

**sunitinib 25 mg capsule, 28**

| 9489K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 3356.15 | 38.80 | Sutent [PF] |

**sunitinib 50 mg capsule, 28**

| 9490L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 6563.05 | 38.80 | Sutent [PF] |

**sunitinib 12.5 mg capsule, 28**

| 9488J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 1736.75 | 38.80 | Sutent [PF] |

## ▪ TRAMETINIB

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***6778***

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition, **AND**
- Patient must not have had progressive disease when treated with a BRAF inhibitor.

**trametinib 2 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10382K | 1 | 3 | .. | 8761.69 | 38.80 | Mekinist [NV] |

**trametinib 500 microgram tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10403M | 3 | 3 | .. | *6608.62 | 38.80 | Mekinist [NV] |

## ▪ TRAMETINIB

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***6752***

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition, **AND**
- Patient must have stable or responding disease.

**trametinib 2 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10405P | 1 | 5 | .. | 8761.69 | 38.80 | Mekinist [NV] |

**trametinib 500 microgram tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10385N | 3 | 5 | .. | *6608.62 | 38.80 | Mekinist [NV] |

## ▪ VEMURAFENIB

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***6044***

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must not have been treated previously with PBS subsidised therapy; OR
- Patient must have developed intolerance to another BRAF inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

**vemurafenib 240 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11076Y | 4 | 3 | .. | *8187.59 | 38.80 | Zelboraf [RO] |

## ▪ VEMURAFENIB

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***6013***

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have stable or responding disease.

**vemurafenib 240 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11081F | 4 | 5 | .. | *8187.59 | 38.80 | Zelboraf [RO] |

*Other antineoplastic agents*

## ▪ HYDROXYUREA

**hydroxyurea 500 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3093T | 1 | 3 | .. | 71.58 | 38.80 | Hydrea [BQ] |

## ▪ IDELALISIB

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

**Authority required**

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with rituximab, **AND**
- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The condition must be CD20 positive, **AND**
- Patient must have a total cumulative illness rating scale (CIRS) score of greater than 6 (excluding CLL-induced illness or organ damage), **AND**
- Patient must be inappropriate for chemo-immunotherapy.

A patient can be considered inappropriate for chemo-immunotherapy when one or more of the following are experienced:

1. Severe neutropenia defined as absolute neutrophil count of less than or equal to 1.0 x $10^9$/L; or
2. Severe thrombocytopenia defined as platelet count of less than or equal to 50 x $10^9$/L; or
3. Evidence of one or more 17p chromosomal deletions demonstrated by fluorescence in situ hybridisation (FISH).

Full blood count results must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

a) A completed authority prescription form;

b) A completed CLL/SLL PBS Authority Application - Supporting information form; and

c) Pathology report indicating that the patient can be considered inappropriate for chemo-immunotherapy due to one or more of the following:

1) Recent severe neutropenia; or
2) Recent severe thrombocytopenia; or
3) Presence of 17p chromosomal deletion using fluorescence in situ hybridisation (FISH).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be in combination with rituximab, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**idelalisib 100 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11170X | 1 | 5 | .. | 5367.27 | 38.80 | Zydelig [GI] |

**idelalisib 150 mg tablet, 60**

| 11162L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 5367.27 | 38.80 | Zydelig [GI] |

## ▪ IDELALISIB

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

**Authority required**

Refractory follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be refractory to a prior therapy with rituximab, **AND**
- The condition must be refractory to a prior therapy with an alkylating agent, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition.

The condition is considered refractory to a prior therapy when the patient experiences less than a partial response or progression of disease within 6 months after completion of the prior therapy.

The condition is considered refractory to both rituximab and an alkylating agent if the agents were administered together or in successive treatment regimens.

The authority application must be made in writing and must include:

a) A completed authority prescription form; and

b) A completed Refractory follicular B-cell non-Hodgkin's lymphoma PBS Authority Application - Supporting information form which must include date of completion of prior therapies with rituximab and an alkylating agent.

**Note** Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe this drug should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Refractory follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**idelalisib 100 mg tablet, 60**

| 11171Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 5367.27 | 38.80 | Zydelig [GI] |

**idelalisib 150 mg tablet, 60**

| 11165P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 5367.27 | 38.80 | Zydelig [GI] |

## ▪ OLAPARIB

**Note** Special Pricing Arrangements apply.

**Authority required**

High grade serous ovarian cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be platinum sensitive, **AND**
- Patient must have received at least two previous platinum-containing regimens, **AND**
- Patient must have relapsed following a previous platinum-containing regimen, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

**Population criteria:**

- Patient must have evidence of a germline class 4 or 5 BRCA1 or BRCA2 gene mutation.

Platinum sensitivity is defined as disease progression greater than 6 months after completion of the penultimate platinum regimen.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline testing.

**Authority required**

High grade serous fallopian tube cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be platinum sensitive, **AND**
- Patient must have received at least two previous platinum-containing regimens, **AND**
- Patient must have relapsed following a previous platinum-containing regimen, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

**Population criteria:**

- Patient must have evidence of a germline class 4 or 5 BRCA1 or BRCA2 gene mutation.

Platinum sensitivity is defined as disease progression greater than 6 months after completion of the penultimate platinum regimen.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline testing.

**Authority required**

High grade serous primary peritoneal cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be platinum sensitive, **AND**
- Patient must have received at least two previous platinum-containing regimens, **AND**
- Patient must have relapsed following a previous platinum-containing regimen, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

**Population criteria:**

- Patient must have evidence of a germline class 4 or 5 BRCA1 or BRCA2 gene mutation.

Platinum sensitivity is defined as disease progression greater than 6 months after completion of the penultimate platinum regimen.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline testing.

**olaparib 50 mg capsule, 4 x 112**

11034R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 6959.52 | 38.80 | Lynparza [AP] |

## ▪ OLAPARIB

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***6715***

High grade serous ovarian cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not have progressive disease.

**Authority required (STREAMLINED)**

***6705***

High grade serous fallopian tube cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not have progressive disease.

**Authority required (STREAMLINED)**

***6716***

High grade serous primary peritoneal cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not have progressive disease.

**olaparib 50 mg capsule, 4 x 112**

11050N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 6959.52 | 38.80 | Lynparza [AP] |

## ▪ VISMODEGIB

**Caution** Vismodegib is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 9 months and 2 months period after cessation of treatment for female and male patients respectively, as according to the TGA approved Product Information.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Metastatic or locally advanced basal cell carcinoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be inappropriate for surgery, **AND**
- The condition must be inappropriate for curative radiotherapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

The authority application must be made in writing and must include:

a) A completed authority prescription form; and

b) a completed Basal Cell Carcinoma Initial PBS Authority Application Form - Supporting Information Form; and

c) A histological confirmation of BCC and whether the condition is metastatic or locally advanced; and

d) A letter from a surgically qualified clinician demonstrating inappropriateness for surgery for patients with locally advanced BCC; and

e) A letter from a radiation oncologist demonstrating inappropriateness for curative radiotherapy for patients with locally advanced BCC; and

f) A signed patient acknowledgement.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

**Inappropriate for surgery is defined as:**

i/ Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or

ii/ Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or

iii/ Medical contraindication to surgery

**Inappropriate for curative radiotherapy is defined as:**

i/Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

ii/ Limitations due to location of tumour; or

iii/ Limitations due to cumulative prior radiotherapy dose; or

iv/ Progressive disease despite prior irradiation of locally advanced BCC.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Metastatic or locally advanced basal cell carcinoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received an authority prescription for this condition with this drug, **AND**
- The condition must not have progressed, **AND**
- The condition must remain inappropriate for surgery, **AND**
- The condition must remain inappropriate for curative radiotherapy, **AND**
- Patient must not receive more than 16 weeks of treatment per continuing treatment under this restriction.

The authority application must be made in writing and must include:

a) A completed authority prescription form; and

b) A completed Basal Cell Carcinoma Continuing PBS Authority Application Form - Supporting Information Form; and

c) A confirmation statement from the treating doctor that the disease has not progressed; and

d) In patients with locally advanced BCC, a letter from a surgically qualified clinician demonstrating that the condition remains inappropriate for surgery; or a letter from a radiation oncologist demonstrating that the condition remains inappropriate for curative radiotherapy.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

**Inappropriate for surgery is defined as:**

i/ Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or

ii/ Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or

iii/ Medical contraindication to surgery

**Inappropriate for curative radiotherapy is defined as:**

i/Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

ii/ Limitations due to location of tumour; or

iii/ Limitations due to cumulative prior radiotherapy dose; or

iv/ Progressive disease despite prior irradiation of locally advanced BCC.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Metastatic or locally advanced basal cell carcinoma

Treatment Phase: Initial treatment or Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete maximum of 16 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete maximum of 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**vismodegib 150 mg capsule, 28**

11070P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 7449.52 | 38.80 | Erivedge [RO] |

## ▪ VORINOSTAT

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

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

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**Authority required**

Cutaneous T-cell lymphoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have received systemic treatment with chemotherapy, **AND**
- Patient must demonstrate relapsed or chemotherapy-refractory disease, **AND**
- Patient must be ineligible for stem cell transplant, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed cutaneous T-cell lymphoma (CTCL) initial PBS Authority Application - Supporting Information Form.

**vorinostat 100 mg capsule, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11138F | 1 | 2 | .. | 4451.64 | 38.80 | Zolinza [MK] |

## ▪ VORINOSTAT

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

**Authority required**

Cutaneous T-cell lymphoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**vorinostat 100 mg capsule, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11141J | 1 | 1 | .. | 4451.64 | 38.80 | Zolinza [MK] |

# ▪ ENDOCRINE THERAPY

## HORMONES AND RELATED AGENTS

*Progestogens*

## ▪ MEDROXYPROGESTERONE

**Restricted benefit**

Advanced breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**medroxyprogesterone acetate 500 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2728N | 1 | 2 | .. | 136.20 | 38.80 | Provera [PF] |

## ▪ MEDROXYPROGESTERONE

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**Restricted benefit**

Endometrial cancer

**medroxyprogesterone acetate 100 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2725K | 1 | 2 | .. | 98.72 | 38.80 | Provera [PF] |

**medroxyprogesterone acetate 200 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2316X | 1 | 2 | .. | 110.78 | 38.80 | Provera [PF] |

**medroxyprogesterone acetate 250 mg tablet, 60**

| 2727M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 136.20 | 38.80 | Provera [PF] |

*Gonadotropin releasing hormone analogues*

## ▪ GOSERELIN

**Restricted benefit**

Carcinoma of the prostate

**Clinical criteria:**

- The condition must be locally advanced (stage C); OR
- The condition must be metastatic (stage D).

**goserelin 10.8 mg implant, 1**

| 8093Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 1050.60 | 38.80 | Zoladex 10.8 Implant [AP] |

## ▪ GOSERELIN

**Restricted benefit**

Carcinoma of the prostate

**Clinical criteria:**

- The condition must be locally advanced (stage C); OR
- The condition must be metastatic (stage D).

**Restricted benefit**

Endometriosis

**Clinical criteria:**

- The condition must be visually proven, **AND**
- The treatment must be for the short-term (up to 6 months).

**Note** Only 1 course of not more than 6 months' therapy will be authorised.

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**goserelin 3.6 mg implant, 1**

| 1454M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 308.20 | 38.80 | Zoladex Implant [AP] |

## ▪ GOSERELIN (&) BICALUTAMIDE

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

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

**Restricted benefit**

Carcinoma of the prostate

**Clinical criteria:**

- The condition must be metastatic (stage D), **AND**
- Patient must require a combination of an antiandrogen and a GnRH (LH-RH) agonist.

**goserelin 10.8 mg implant [1 implant] (&) bicalutamide 50 mg tablet [84 tablets], 1 pack**

| 9066E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 1467.19 | 38.80 | ZolaCos CP 10.8/50(84) [AP] |

**goserelin 3.6 mg implant [1 implant] (&) bicalutamide 50 mg tablet [28 tablets], 1 pack**

| 9064C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 5 | .. | 457.51 | 38.80 | ZolaCos CP 3.6/50 [AP] |

**goserelin 10.8 mg implant [1 implant] (&) bicalutamide 50 mg tablet [28 tablets], 1 pack**

| 9065D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 1189.46 | 38.80 | ZolaCos CP 10.8/50(28) [AP] |

## ▪ LEUPRORELIN

**Restricted benefit**

Central precocious puberty

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a paediatric endocrinologist; OR
- Must be treated by a medical practitioner in consultation with an endocrinologist specialising in paediatrics.

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition.

**leuprorelin acetate 30 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack**

| 10255R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 1374.48 | 38.80 | Lucrin Depot Paediatric 30 mg PDS [VE] |

## ▪ LEUPRORELIN

**Restricted benefit**

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

**leuprorelin acetate 30 mg injection: modified release [1] (&) inert substance diluent [2 mL syringe], 1 pack**

| 8877F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 1374.48 | 38.80 | Lucrin Depot 4 Month PDS [VE] |

**leuprorelin acetate 45 mg injection: modified release [1] (&) inert substance diluent [1 syringe], 1 pack**

| 10656W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 2021.67 | 38.80 | Lucrin Depot 6-Month [VE] |

**leuprorelin acetate 45 mg injection: modified release [1] (&) inert substance diluent [1 syringe], 1 pack**

| 8859G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 2021.67 | 38.80 | Eligard 6 month [TL] |

**leuprorelin acetate 7.5 mg injection: modified release [1] (&) inert substance diluent [2 mL syringe], 1 pack**

| 8875D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 393.95 | 38.80 | Lucrin Depot 7.5mg PDS [VE] |

**leuprorelin acetate 22.5 mg injection: modified release [1] (&) inert substance diluent [2 mL syringe], 1 pack**

| 8876E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 1050.60 | 38.80 | Lucrin Depot 3 Month PDS [VE] |

**leuprorelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack**

| 8708H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 1050.60 | 38.80 | Eligard 3 month [TL] |

**leuprorelin acetate 7.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack**

| 8707G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 393.95 | 38.80 | Eligard 1 month [TL] |

**leuprorelin acetate 30 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack**

| 8709J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 1374.48 | 38.80 | Eligard 4 month [TL] |

## ▪ LEUPRORELIN

**Restricted benefit**

Central precocious puberty

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a paediatric endocrinologist; OR
- Must be treated by an endocrinologist specialising in paediatrics.

**Population criteria:**

- Patient must be aged 10 years or younger (girls) or 11 years or younger (boys), **AND**
- Patient must have had onset of signs or symptoms of central precocious puberty prior to the age of 8 years (girls) or 9 years (boys).

**Restricted benefit**

Central precocious puberty

Treatment Phase: Initial - grandfather

**Clinical criteria:**

- Patient must have received treatment with a gonadotropin releasing hormone analogue (GnRHa) for this condition prior to 1 May 2015.

**Treatment criteria:**

- Must be treated by a paediatric endocrinologist; OR
- Must be treated by an endocrinologist specialising in paediatrics.

**leuprorelin acetate 30 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10256T | 1 | 1 | .. | 1374.48 | 38.80 | Lucrin Depot Paediatric 30 mg PDS [VE] |

## ▪ LEUPRORELIN (&) INERT SUBSTANCE (&) BICALUTAMIDE

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

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

**Restricted benefit**

Carcinoma of the prostate

**Clinical criteria:**

- The condition must be metastatic (stage D), **AND**
- Patient must require a combination of an antiandrogen and a GnRH (LH-RH) agonist.

**leuprorelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [84], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10969H | ‡1 | 1 | .. | 1268.94 | 38.80 | Bi ELIGARD CP [TL] |

**leuprorelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [28], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10963B | ‡1 | .. | .. | 1123.38 | 38.80 | Bi ELIGARD CP [TL] |

**leuprorelin acetate 7.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [28], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10962Y | ‡1 | 5 | .. | 472.21 | 38.80 | Bi ELIGARD CP [TL] |

## ▪ TRIPTORELIN

**Restricted benefit**

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

**triptorelin 3.75 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9378N | 1 | 5 | .. | 393.95 | 38.80 | Diphereline [IS] |

**triptorelin 22.5 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5297T | 1 | .. | .. | 2021.67 | 38.80 | Diphereline [IS] |

**triptorelin 11.25 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9379P | 1 | 1 | .. | 1050.60 | 38.80 | Diphereline [IS] |

# HORMONE ANTAGONISTS AND RELATED AGENTS

*Anti-estrogens*

## ▪ TAMOXIFEN

**Note** This pharmaceutical benefit is not PBS-subsidised for primary prevention of breast cancer.

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

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**tamoxifen 10 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2109B NP | 1 | 5 | .. | 20.05 | 21.26 | Genox 10 [AF] |

## ▪ TAMOXIFEN

**Note** For item codes 2110C and 1880Y, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

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

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**tamoxifen 20 mg tablet, 30**

1880Y (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *26.61 | 27.82 | [a] Nolvadex-D [AP] |

## ▪ TAMOXIFEN

**Note** This pharmaceutical benefit is not PBS-subsidised for primary prevention of breast cancer.

**Note** For item codes 2110C and 1880Y, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

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

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**tamoxifen 20 mg tablet, 60**

2110C (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 26.62 | 27.83 | [a] Genox 20 [AF] | [a] GenRx Tamoxifen [GX] |
| | | | | | [a] Tamosin [QA] | [a] Tamoxifen Sandoz [SZ] |

## ▪ TAMOXIFEN

**Note** A moderate risk of developing breast cancer is if the lifetime breast cancer risk is 1.5 to 3 times the population average. A high risk of developing breast cancer is if the lifetime breast cancer risk is more than 3 times the population average.

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

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

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

**Restricted benefit**

Reduction of breast cancer risk

**Clinical criteria:**

- Patient must have a moderate or high risk of developing breast cancer, **AND**
- The treatment must not exceed a dose of 20 mg per day, **AND**
- The treatment must not exceed a lifetime maximum of 5 years for this condition.

**tamoxifen 20 mg tablet, 30**

10911G (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 18.85 | 20.06 | [a] Genox 20 [AF] | [a] Nolvadex-D [AP] |

## ▪ TOREMIFENE

**toremifene 60 mg tablet, 30**

8216K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 69.23 | 38.80 | Fareston [AS] |

*Anti-androgens*

## ▪ BICALUTAMIDE

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

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

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

**Authority required (STREAMLINED)**

***5729***

Metastatic (stage D) carcinoma of the prostate

**Clinical criteria:**

- The treatment must be in combination with GnRH (LH-RH) analogue therapy.

**bicalutamide 50 mg tablet, 28**

8094B (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 56.89 | 38.80 | [a] APO-Bicalutamide [TX]<br>[a] Bicalox [ER]<br>[a] Calutex [QA]<br>[a] Cosudex [AP] | [a] Bicalide [JU]<br>[a] Bicalutamide AN [EA]<br>[a] Cosamide 50 [AF] |

## ▪ CYPROTERONE

**cyproterone acetate 100 mg tablet, 50**

8019C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 66.87 | 38.80 | [a] ANTERONE 100 [RW]<br>[a] Cyprone 100 [AF]<br>[a] Cyproterone AN [EA]<br>[a] GenRx Cyproterone Acetate [GX] | [a] Cyprocur 100 [QA]<br>[a] Cyprostat-100 [SY]<br>[a] Cyproterone Sandoz [HX]<br>[a] Procur 100 [ED] |
| | | [B]1.41 | 68.28 | 38.80 | [a] Androcur-100 [BN] | |

**cyproterone acetate 50 mg tablet, 50**

1270W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *82.69 | 38.80 | [a] ANTERONE 50 [RW]<br>[a] Cyprone [AF]<br>[a] Cyproterone AN [EA]<br>[a] Cyrotone [ER] | [a] Cyprocur 50 [QA]<br>[a] Cyprostat [SY]<br>[a] Cyproterone Sandoz [HX]<br>[a] GenRx Cyproterone Acetate [GX] |
| | | [B]2.28 | *84.97 | 38.80 | [a] Androcur [BN] | |

## ▪ ENZALUTAMIDE

**Note** Special Pricing Arrangements apply.

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

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

**Authority required**

Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**

- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have failed treatment with docetaxel due to resistance or intolerance; OR
- Patient must be unsuitable for docetaxel treatment on the basis of predicted intolerance to docetaxel, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must not have received prior treatment with abiraterone; OR
- Patient must have developed intolerance to abiraterone of a severity necessitating permanent treatment withdrawal.

**enzalutamide 40 mg capsule, 112**

10174L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 3702.82 | 38.80 | Xtandi [LL] |

## ▪ FLUTAMIDE

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

**Note Shared Care Model**:

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

**Authority required (STREAMLINED)**

***6611***

Metastatic (stage D) carcinoma of the prostate

**Clinical criteria:**

- The treatment must be in combination with GnRH (LH-RH) analogue therapy.

**flutamide 250 mg tablet, 30**

2742H (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *154.30 | 38.80 | Flutamide MYLAN [AF] |

## ▪ FLUTAMIDE

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

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

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

**Authority required (STREAMLINED)**

***5816***

Metastatic (stage D) carcinoma of the prostate

**Clinical criteria:**

- The treatment must be in combination with GnRH (LH-RH) analogue therapy.

**flutamide 250 mg tablet, 100**

| 1417N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 170.37 | 38.80 | Flutamin [AF] |

## ▪ LEUPRORELIN (&) INERT SUBSTANCE (&) BICALUTAMIDE

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

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

**Restricted benefit**

Carcinoma of the prostate

**Clinical criteria:**

- The condition must be metastatic (stage D), **AND**
- Patient must require a combination of an antiandrogen and a GnRH (LH-RH) agonist.

**leuprorelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [84], 1 pack**

| 10969H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 1268.94 | 38.80 | Bi ELIGARD CP [TL] |

**leuprorelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [28], 1 pack**

| 10963B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 1123.38 | 38.80 | Bi ELIGARD CP [TL] |

**leuprorelin acetate 7.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [28], 1 pack**

| 10962Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 5 | .. | 472.21 | 38.80 | Bi ELIGARD CP [TL] |

## ▪ NILUTAMIDE

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

**Authority required (STREAMLINED)**

***5785***

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

**Clinical criteria:**

- The treatment must be in combination with GnRH (LH-RH) analogue therapy.

**Authority required (STREAMLINED)**

***5647***

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

**Clinical criteria:**

- The treatment must be in conjunction with surgical orchidectomy.

**nilutamide 150 mg tablet, 30**

| 8131Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 213.38 | 38.80 | Anandron [SW] |

*Aromatase inhibitors*

## ▪ ANASTROZOLE

**Note** This drug is not PBS-subsidised for primary prevention of breast cancer.

**Note** This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**anastrozole 1 mg tablet, 30**

8179L (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 29.13 | 30.34 | [a] Anastrol [QA] | [a] Anastrozole AN [EA] |
| | | | | | [a] Anastrozole FBM [FO] | [a] Anastrozole GH [GQ] |
| | | | | | [a] Anastrozole Sandoz [SZ] | [a] APO-Anastrozole [TX] |
| | | | | | [a] Arianna 1 [AF] | [a] Arimidex [AP] |
| | | | | | [a] Astzol [JU] | [a] Azastrole [ER] |

## ▪ EXEMESTANE

**Restricted benefit**

Metastatic (Stage IV) breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- Patient must be receiving PBS-subsidised everolimus concomitantly for this condition.

**Population criteria:**

- Patient must not be pre-menopausal.

**exemestane 25 mg tablet, 30**

10103R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 66.59 | 38.80 | [a] APO-Exemestane [TX] | [a] Estamane [JU] |
| | | | | | [a] Exaccord [RA] | [a] Exemestane AN [EA] |
| | | | | | [a] Exemestane GH [GQ] | [a] Exemestane Sandoz [SZ] |
| | | [B]4.00 | 70.59 | 38.80 | [a] Aromasin [PF] | |

## ▪ EXEMESTANE

**Note** This drug is not PBS-subsidised for primary prevention of breast cancer.

**Note** This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years, i.e. a patient who has received 2 years of tamoxifen therapy may only receive 3 years of PBS-subsidised treatment with exemestane.

**Note Shared Care Model**:

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

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**exemestane 25 mg tablet, 30**

8506Q (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 66.59 | 38.80 | [a] APO-Exemestane [TX] | [a] Estamane [JU] |
| | | | | | [a] Exaccord [RA] | [a] Exemestane AN [EA] |
| | | | | | [a] Exemestane GH [GQ] | [a] Exemestane Sandoz [SZ] |
| | | [B]4.00 | 70.59 | 38.80 | [a] Aromasin [PF] | |

## ▪ LETROZOLE

**Note** This drug is not PBS-subsidised for primary prevention of breast cancer.

**Note** This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

**Note Shared Care Model**:

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

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**letrozole 2.5 mg tablet, 30**

8245Y (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 30.88 | 32.09 | [a] APO-Letrozole [TX]<br>[a] Femara 2.5 mg [NV]<br>[a] Fera [QA]<br>[a] Letroz [JU]<br>[a] Letrozole FBM [FO]<br>[a] Letrozole RBX [RA]<br>[a] Pharmacor Letrozole 2.5 [CR] | [a] Chem mart Letrozole [CH]<br>[a] Femolet [AF]<br>[a] Gynotril [ER]<br>[a] Letrozole AN [EA]<br>[a] Letrozole generichealth [GQ]<br>[a] Letrozole Sandoz [SZ]<br>[a] Terry White Chemists Letrozole [TW] |

*Other hormone antagonists and related agents*

## ▪ ABIRATERONE

**Note** Special Pricing Arrangements apply.

**Authority required**

Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**

- The treatment must be used in combination with a corticosteroid, **AND**
- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have failed treatment with docetaxel due to resistance or intolerance; OR
- Patient must be unsuitable for docetaxel treatment on the basis of predicted intolerance to docetaxel, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not receive PBS-subsidised abiraterone if progressive disease develops while on abiraterone, **AND**
- Patient must not have received prior treatment with enzalutamide; OR
- Patient must have developed intolerance to enzalutamide of a severity necessitating permanent treatment withdrawal.

**abiraterone acetate 250 mg tablet, 120**

2698B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 3603.06 | 38.80 | Zytiga [JC] |

## ▪ DEGARELIX

**Restricted benefit**

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

**degarelix 80 mg injection [1 vial] (&) inert substance diluent [1 syringe], 1 pack**

2784M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 393.95 | 38.80 | Firmagon 80mg [FP] |

## ▪ DEGARELIX

**Note** No applications for increased maximum quantities and/or repeats will be authorised for the 120 mg powder for injection.

**Restricted benefit**

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

**degarelix 120 mg injection [2 vials] (&) inert substance diluent [2 syringes], 1 pack**

2785N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 412.15 | 38.80 | Firmagon 120mg [FP] |

# ▪ IMMUNOSTIMULANTS

## IMMUNOSTIMULANTS

*Interferons*

## ▪ INTERFERON ALFA-2A

**Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required**

Myeloproliferative disease

**Clinical criteria:**

- Patient must have excessive thrombocytosis.

**interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe**

8553E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | 4 | .. | *477.25 | 38.80 | Roferon-A [RO] |

## ▪ INTERFERON ALFA-2A

**Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required**

Low grade non-Hodgkin's lymphoma

**Clinical criteria:**

- The condition must have clinical features suggestive of a poor prognosis, **AND**
- The treatment must be in combination with anthracycline-based chemotherapy.

**interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe**

8181N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 15 | 5 | .. | *477.40 | 38.80 | Roferon-A [RO] |

**interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe**

8184R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | 5 | .. | *477.25 | 38.80 | Roferon-A [RO] |

## ▪ INTERFERON ALFA-2A

**Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required**

Hairy cell leukaemia

**Authority required**

Myeloproliferative disease

**Clinical criteria:**

- Patient must have excessive thrombocytosis.

**interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe**

8180M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 15 | 4 | .. | *477.40 | 38.80 | Roferon-A [RO] |

## ▪ INTERFERON ALFA-2B

**Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required**

Hairy cell leukaemia

**interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL**

8572E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 4 | .. | *571.66 | 38.80 | Intron A Redipen [MK] |

## ▪ INTERFERON ALFA-2B

**Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required**

Multiple myeloma

Treatment Phase: Maintenance treatment

**Clinical criteria:**

- The condition must be in remission following chemotherapy.

**Authority required**

Low grade non-Hodgkin's lymphoma

**Clinical criteria:**

- The condition must have clinical features suggestive of a poor prognosis, **AND**
- The treatment must be in combination with anthracycline-based chemotherapy.

**interferon alfa-2b 30 million units/1.2 mL injection, 1.2 mL**

8476D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *949.60 | 38.80 | Intron A Redipen [MK] |

**interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL**

8348J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *571.66 | 38.80 | Intron A Redipen [MK] |

## ▪ INTERFERON BETA-1A

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

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

**Authority required (STREAMLINED)**

***4881***

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required (STREAMLINED)**

***6860***

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**interferon beta-1a 44 microgram/0.5 mL (12 million units) injection, 12 x 0.5 mL syringes**

8403G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 998.56 | 38.80 | Rebif 44 [SG] |

**interferon beta-1a 132 microgram/1.5 mL (12 million units) injection, 4 x 1.5 mL cartridges**

9332E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 998.56 | 38.80 | Rebif 44 [SG] |

**INTERFERON BETA-1a Injection 44 micrograms (12,000,000 i.u.) in 0.5 mL single dose autoinjector, 12**

8968B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 998.56 | 38.80 | Rebif 44 [SG] |

**interferon beta-1a 6 million units (30 microgram)/0.5 mL injection, 4 x 0.5 mL syringes**

8805K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 998.56 | 38.80 | Avonex [BD] |

## ▪ INTERFERON BETA-1B

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

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

**Authority required (STREAMLINED)**

***4881***

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required (STREAMLINED)**

***6860***

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**interferon beta-1b 8 million international units (250 microgram) injection [15 x 250 microgram vials] (&) inert substance diluent [15 x 1.2 mL syringes], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8101J | 1 | 5 | .. | 994.39 | 38.80 | Betaferon [BN] |

## ▪ PEGINTERFERON ALFA-2A

**Caution** Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

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

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

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11037X NP | 1 | 2 | .. | 1404.79 | 38.80 | Pegasys [RO] |

## ▪ PEGINTERFERON BETA-1A

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

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

**Authority required (STREAMLINED)**

***4881***

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL injection devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10212L | 1 | 4 | .. | 1050.09 | 38.80 | Plegridy [BD] |

**peginterferon beta-1a 63 microgram/0.5 mL injection [0.5 mL injection device] (&) peginterferon beta-1a 94 microgram/0.5 mL injection [0.5 mL injection device], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10218T | ‡1 | .. | .. | 1050.09 | 38.80 | Plegridy [BD] |

## ▪ PEGINTERFERON BETA-1A

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

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

**Authority required (STREAMLINED)**

***6860***

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL injection devices**

| 10220X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 1050.09 | 38.80 | Plegridy [BD] |

*Other immunostimulants*

## ▪ BACILLUS CALMETTE AND GUERIN-TICE STRAIN

**Restricted benefit**

Primary and relapsing superficial urothelial carcinoma of the bladder

**Bacillus Calmette and Guerin-Tice strain 500 million colony forming units injection, 3 vials**

| 1131M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 524.75 | 38.80 | OncoTICE [MK] |

## ▪ GLATIRAMER ACETATE

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

**Authority required (STREAMLINED)**

***4881***

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required (STREAMLINED)**

***6860***

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**glatiramer acetate 40 mg/mL injection, 12 x 1 mL syringes**

| 10416F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 1035.03 | 38.80 | Copaxone [TB] |

**glatiramer acetate 20 mg/mL injection, 28 x 1 mL syringes**

| 8726G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 1035.03 | 38.80 | Copaxone [TB] |

# ▪ IMMUNOSUPPRESSANTS

## IMMUNOSUPPRESSANTS

*Selective immunosuppressants*

## ▪ ABATACEPT

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**

- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

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

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the

baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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

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

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**abatacept 125 mg/mL injection, 4 x 1 mL syringes**

11068M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 953.23 | 38.80 | Orencia ClickJect [BQ] |

**abatacept 125 mg/mL injection, 4 x 1 mL syringes**

1221G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 953.23 | 38.80 | Orencia [BQ] |

## ▪ ABATACEPT

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) completed authority prescription forms; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

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

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New

baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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

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

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) completed authority prescription forms; and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with this drugt and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

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

If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is

sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is

important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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

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

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**abatacept 125 mg/mL injection, 4 x 1 mL syringes**

| 11092T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 953.23 | 38.80 | Orencia ClickJect [BQ] |

**abatacept 125 mg/mL injection, 4 x 1 mL syringes**

| 1220F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 953.23 | 38.80 | Orencia [BQ] |

## ▪ EVEROLIMUS

**Caution** Careful monitoring of patients is mandatory.

**everolimus 750 microgram tablet, 60**

| 8842J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 3 | .. | *1494.83 | 38.80 | Certican [NV] |

**everolimus 1 mg tablet, 60**

| 9352F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 3 | .. | *1967.37 | 38.80 | Certican [NV] |

**everolimus 500 microgram tablet, 60**

8841H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 512.87 | 38.80 | Certican [NV] |

**everolimus 250 microgram tablet, 60**

8840G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 258.84 | 38.80 | Certican [NV] |

## ▪ FINGOLIMOD

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

**Authority required**
Multiple sclerosis
Treatment Phase: Initial treatment
**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required**
Multiple sclerosis
Treatment Phase: Continuing treatment
**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**fingolimod 500 microgram capsule, 28**

5262Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 2207.81 | 38.80 | Gilenya [NV] |

## ▪ LEFLUNOMIDE

**Caution** Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

**Authority required (STREAMLINED)**
***5766***
Severe active psoriatic arthritis
**Clinical criteria:**

- Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR
- Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, **AND**
- The treatment must be initiated by a physician.

**leflunomide 20 mg tablet, 30**

5450W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 43.93 | 38.80 | [a] Arabloc [AV]<br>[a] Ataris 20 [AF]<br>[a] Leflunomide Sandoz [SZ] | [a] Arava [SW]<br>[a] Leflunomide APOTEX [GX] |

**leflunomide 10 mg tablet, 30**

5449T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 32.65 | 33.86 | [a] Arabloc [AV]<br>[a] Ataris 10 [AF]<br>[a] Leflunomide Sandoz [SZ] | [a] Arava [SW]<br>[a] Leflunomide APOTEX [GX] |

## ▪ LEFLUNOMIDE

**Caution** Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

**Authority required (STREAMLINED)**

***5681***

Severe active rheumatoid arthritis

**Clinical criteria:**

- Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR
- Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, **AND**
- The treatment must be initiated by a physician.

**leflunomide 20 mg tablet, 30**

8375T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 43.93 | 38.80 | [a] APO-Leflunomide [TX]<br>[a] Arava [SW]<br>[a] Leflunomide AN [EA]<br>[a] Leflunomide-GA [ED]<br>[a] Leflunomide Sandoz [SZ] | [a] Arabloc [AV]<br>[a] Ataris 20 [AF]<br>[a] Leflunomide APOTEX [GX]<br>[a] Leflunomide GH [GQ]<br>[a] Lunava 20 [ZP] |

**leflunomide 10 mg tablet, 30**

8374R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 32.65 | 33.86 | [a] APO-Leflunomide [TX]<br>[a] Arava [SW]<br>[a] Leflunomide AN [EA]<br>[a] Leflunomide-GA [ED]<br>[a] Leflunomide Sandoz [SZ] | [a] Arabloc [AV]<br>[a] Ataris 10 [AF]<br>[a] Leflunomide APOTEX [GX]<br>[a] Leflunomide GH [GQ]<br>[a] Lunava 10 [ZP] |

## ▪ MYCOPHENOLATE

**Caution** Careful monitoring of patients is mandatory.

**mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL**

8651H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | #279.62 | 38.80 | CellCept [RO] |

**mycophenolate 360 mg enteric tablet, 120**

2193K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 195.71 | 38.80 | Myfortic [NV] |

**mycophenolate mofetil 500 mg tablet, 50**

8650G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 5 | .. | *152.89 | 38.80 | [a] APO-Mycophenolate [TX]<br>[a] Ceptolate [AF]<br>[a] Mycophenolate Sandoz [SZ] | [a] CellCept [RO]<br>[a] Mycophenolate AN [EA]<br>[a] Pharmacor Mycophenolate 500 [CR] |

**mycophenolate 180 mg enteric tablet, 120**

2150E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 103.33 | 38.80 | Myfortic [NV] |

## ▪ MYCOPHENOLATE

**Caution** Careful monitoring of patients is mandatory.

**Note** For item codes 8649F and 1836P, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution.

**mycophenolate mofetil 250 mg capsule, 100**

8649F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 5 | .. | *152.95 | 38.80 | [a] APO-Mycophenolate [TX]<br>[a] Mycophenolate Sandoz [SZ] | [a] CellCept [RO]<br>[a] Pharmacor Mycophenolate 250 [CR] |

**mycophenolate Capsule 250 mg, 50**

1836P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 6 | 5 | .. | *152.95 | 38.80 | [a] Ceptolate [AF] |

## ▪ SIROLIMUS

**Caution** Careful monitoring of patients is mandatory.

**sirolimus 2 mg tablet, 100**

| 8833X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 1499.62 | 38.80 | Rapamune [PF] |

**sirolimus 1 mg tablet, 100**

| 8724E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 769.48 | 38.80 | Rapamune [PF] |

**sirolimus 1 mg/mL oral liquid, 60 mL**

| 8725F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 3 | .. | 499.55 | 38.80 | Rapamune [PF] |

**sirolimus 500 microgram tablet, 100**

| 8984W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 387.15 | 38.80 | Rapamune [PF] |

## ▪ TERIFLUNOMIDE

**Caution** Teriflunomide is a category X drug and must not be given to pregnant women or women of childbearing potential who are not currently using reliable contraception.

Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required**

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**teriflunomide 14 mg tablet, 28**

| 2898M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 1837.26 | 38.80 | Aubagio [GZ] |

## ▪ TOFACITINIB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to

Friday).
Written application for authority approval should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure

uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

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

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**tofacitinib 5 mg tablet, 56**

10511F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1267.40 | 38.80 | Xeljanz [PF] |

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**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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

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

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe this drug should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) a completed authority prescription form and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (Grandfather patients)

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have been receiving treatment with this drug for this condition prior to 1 October 2015, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(c) a signed patient acknowledgement.

All applications for treatment with this drug for this condition under this restriction must include baseline joint count and ESR and/or CRP as determined at the completion of a 6 month intensive DMARD trial but prior to ceasing DMARD therapy.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**tofacitinib 5 mg tablet, 56**

| 10517M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 1267.40 | 38.80 | Xeljanz [PF] |

*Tumor necrosis factor alpha (TNF-) inhibitors*

## ▪ ADALIMUMAB

**Note** Special Pricing Arrangements apply.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authority approval for sufficient therapy to complete the balance of supply should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time.
For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.
From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab.
Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.
A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.
A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2015.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to theDepartment of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.
For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure

uninterrupted TNF-alfa antagonist supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient with severe disease may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).
A patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PCDAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.
Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.
A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply for paediatric patient

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under Initial 1 (new patient or patient recommencing treatment after break of more than 5 years) or Initial 2 (change or recommencement of treatment after a break of less than 5 years) or Initial 3 (grandfathered patients) or Continuing treatment to complete the maximum duration of treatment specified in the relevant treatment phase, **AND**
- The treatment must provide no more than the balance of up to 16 weeks of therapy (new patients or change/re-commencement patients; Initial 1 or Initial 2) or 24 weeks of therapy (Continuing patients or Grandfathered patients).

**Treatment criteria:**

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

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

| 10400J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| 10399H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

10422M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 1401.83 | 38.80 | Humira [VE] |

## ▪ ADALIMUMAB

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment 1 - New patient or Initial treatment 2 - Recommencement of treatment – balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment 1 - New patient restriction to complete a maximum of 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment 2 - Recommencement of treatment restriction to complete a maximum of 16 weeks treatment.

**Treatment criteria:**

- Must be treated by a dermatologist.

A maximum of 12 weeks of treatment will be authorised under this restriction.

**adalimumab 40 mg/0.8 mL injection, 4 x 0.8 mL cartridges**

11133Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 2709.24 | 38.80 | Humira [VE] |

## ▪ ADALIMUMAB

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have demonstrated an adequate response to treatment with adalimumab, **AND**
- Patient must have received adalimumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-

bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient adalimumab therapy under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

5284D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

5283C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1401.83 | 38.80 | Humira [VE] |

## ▪ ADALIMUMAB

**Note** Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.
Written applications for authority to prescribe adalimumab should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.
From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.
A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment

cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

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

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

**Note** No applications for increased maximum quantities and/or repeats will be authorised.

**Authority required**

Initial 1

Initial treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has an externally draining enterocutaneous or rectovaginal fistula; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

**Authority required**

Initial 2

Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with adalimumab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and

(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the time frames specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday

to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

| 8965W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| 8963R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL syringes**

| 8961P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 3989.10 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges**

| 8962Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 3989.10 | 38.80 | Humira [VE] |

## ▪ ADALIMUMAB

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

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

weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

**Note** No applications for increased maximum quantities and/or repeats will be authorised.

**Authority required**

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with adalimumab.

Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

(a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with adalimumab prior to 4 November 2010; and

(b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with adalimumab; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) is receiving treatment with adalimumab at the time of application; and

(e) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with adalimumab.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

A maximum of 24 weeks treatment will be approved under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

**Authority required**

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, an assessment of the patient's response must be made following a minimum of 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

8966X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

8964T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1401.83 | 38.80 | Humira [VE] |

## ▪ ADALIMUMAB

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment 1 - New patient

**Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

**Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 1 month old at the time of application.

An assessment of the patient's response to this recommencement course of treatment must be made following a minimum of 12 weeks of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial treatment 1 - New patient or Initial treatment 2 - Recommencement of treatment - balance of supply

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed hidradenitis suppurativa PBS authority application supporting Information form which must include:

(i) the Hurley stage grading; and

(ii) the AN count; and

(iii) the name of the antibiotic/s received for two separate courses each of three months; or

(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics

(v) a signed patient acknowledgement.

**Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment 2 - Recommencement of treatment

**Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

**Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 1 month old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An assessment of the patient's response to this recommencement course of treatment must be made following a minimum of 12 weeks of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial treatment 1 - New patient or Initial treatment 2 - Recommencement of treatment - balance of supply

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed hidradenitis suppurativa PBS authority application supporting Information form which must include:

(i) the Hurley stage grading; and

(ii) the AN count.

**adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges**

11132X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 3989.10 | 38.80 | Humira [VE] |

## ▪ ADALIMUMAB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

For the first application for continuing treatment a Hidradenitis Suppurativa Clinical Response (HiSCR) assessment must be made following a minimum of 12 weeks of treatment. For subsequent continuing treatment a HiSCR assessment must be made every 24 weeks.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and provided to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed hidradenitis suppurativa PBS authority application supporting Information form which must include the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

**Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment 3 - Grandfathered patient

**Clinical criteria:**

- Patient must have been receiving treatment with this drug for this condition prior to 1 July 2017, **AND**
- Patient must have had a Hurley stage II or III with an abscess and inflammatory nodule (AN) count greater than or equal to 3 prior to starting treatment with this drug, **AND**
- Patient must have demonstrated a response to treatment by achieving Hidradenitis Suppurativa Clinical Response (HiSCR) after 12 weeks of treatment if the patient has been treated with this drug for this condition for 12 weeks or longer,

**AND**

- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

For the first application for continuing treatment a Hidradenitis Suppurativa Clinical Response (HiSCR) assessment must be made following a minimum of 12 weeks of treatment. For subsequent continuing treatment a HiSCR assessment must be made every 24 weeks.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and provided to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Assessment of disease severity must be no more than 1 month old at the time treatment with this drug was initiated.

A maximum of 24 weeks treatment will be authorised under this restriction.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria or recommencement of treatment criteria where there is a break in treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) completed hidradenitis suppurativa PBS authority application supporting Information form which must include:

(i) the Hurley stage grading; and

(ii) the AN count; and

(iii) the name of the antibiotic/s received for two separate courses each of three months; or

(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics

(v) the Hidradenitis Suppurativa Clinical Response (HiSCR) result if the patient has received 12 weeks or more of treatment

(vi) a signed patient acknowledgement.

**adalimumab 40 mg/0.8 mL injection, 4 x 0.8 mL cartridges**

11137E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 2709.24 | 38.80 | Humira [VE] |

## ▪ ADALIMUMAB

**Note** No applications for increased maximum quantities will be authorised.

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

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).
Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.
From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.
A patient who received PBS-subsidised adalimumab, infliximab,or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.
A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this

treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.
From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.
For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
(b) Continuing treatment.
Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.
A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.
(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.
A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

**Authority required**

Severe Crohn disease

Treatment Phase: Continuing treatment

**Treatment criteria:**

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

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

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

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

9191R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

9189P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1401.83 | 38.80 | Humira [VE] |

## ▪ ADALIMUMAB

**Note** Special Pricing Arrangements apply.

**Note** No applications for increased maximum quantities will be authorised.

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

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time.
For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.
From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab.
Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.
A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.
A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2015.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to theDepartment of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.
For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an

adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient with severe disease may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).
A patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PCDAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.
Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.
A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

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**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment (new paediatric patient) of Crohn disease in a paediatric patient assessed by PCDAI (Initial 1)

**Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment and which is no more than 1 month old at the time of application.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

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

Applications for authorisation of initial treatment must be in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition; and

(iii) the signed patient or guardian acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Human Services website (www.humanservices.gov.au).

A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) will be authorised.

Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater: one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg: one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these time-frames, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**

Severe Crohn disease

Treatment Phase: Change or re-commencement of treatment of Crohn disease in a paediatric patient assessed by PCDAI (Initial 2)

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must in this treatment cycle, have received prior PBS-subsidised treatment with this drug for this condition; OR
- Patient must in this treatment cycle, have received prior PBS-subsidised treatment with infliximab for this condition and have a current PCDAI score of 40 or greater, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

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

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for

adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Applications for authorisation of initial treatment must be in writing and must include:

(a) two completed authority prescription form; and

(b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and

(ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater: one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg: one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these time-frames, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

10413C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

10419J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL syringes**

10404N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 3989.10 | 38.80 | Humira [VE] |

**adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

10389T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges**

10397F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 3989.10 | 38.80 | Humira [VE] |

## ▪ ADALIMUMAB

**Note** Special Pricing Arrangements apply.

**Note** No applications for increased maximum quantities will be authorised.

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

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time.
For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.
From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab.
Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.
A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.
A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2015.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to theDepartment of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.
For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient with severe disease may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).
A patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.
(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PCDAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

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**Authority required**

Severe Crohn disease

Treatment Phase: Initial PBS-subsidised treatment of Crohn disease in a paediatric patient who has previously received non-PBS-subsidised therapy with this drug (Initial 3 - Grandfather)

**Treatment criteria:**

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

**Clinical criteria:**

- Patient must have been receiving treatment with this drug prior to 1 August 2015, **AND**
- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have had disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on prior conventional treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug as defined as a reduction in PCDAI Score by at least 15 points as compared to baseline and a total of PCDAI score of 40 points or less with the PCDAI assessment being no more than 1 month old at the time of application.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:

(i) the completed current and baseline Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet;

(ii) the date of commencement of this drug; and

(iii) the signed patient or guardian acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

The patient's current PCDAI assessment must be no more than 1 month old at the time of application. The baseline PCDAI assessment must be from immediately prior to commencing treatment with this drug.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

A maximum of 24 weeks treatment will be approved under this criterion.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction.

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

**Authority required**

Severe Crohn disease

Treatment Phase: Continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug as defined as a reduction in PCDAI Score by at least 15 points as compared to baseline and a total of PCDAI score of 40 points or less with the PCDAI assessment being no more than 1 month old at the time of application.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

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

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:

(i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, a PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

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

A maximum of 24 weeks treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

10420K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

10412B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

10396E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1401.83 | 38.80 | Humira [VE] |

## ▪ ADALIMUMAB

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR
- Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with adalimumab for this condition in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

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

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a

treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient adalimumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient adalimumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

5282B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

5281Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1401.83 | 38.80 | Humira [VE] |

## ▪ ADALIMUMAB

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

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:
(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L; or
(c) an ESR or CRP measurement reduced by at least 20% from baseline.
Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.
The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.
All measurements provided must be no more than 1 month old at the time of application.
A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.
All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

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

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

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

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

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

(1) How to prescribe PBS-subsidised bDMARD therapy

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Grandfather patients - secukinumab only.

For patients who commenced treatment with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction

(c) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised

baseline measurements.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9104E | 1 | 5 | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9078T | 1 | 5 | .. | 1401.83 | 38.80 | Humira [VE] |

## ▪ ADALIMUMAB

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

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

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-

subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment

applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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

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

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9100Y | 1 | 5 | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8741C | 1 | 5 | .. | 1401.83 | 38.80 | Humira [VE] |

## ▪ ADALIMUMAB

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

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

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

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

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to

24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

| 9102C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| 9034L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 1401.83 | 38.80 | Humira [VE] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of infliximab, vedolizumab and adalimumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either infliximab, vedolizumab or adalimumab at any one time. From 1 December 2016, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial each of PBS-subsidised infliximab, vedolizumab or adalimumab without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with infliximab, vedolizumab or adalimumab while they continue to show a response to therapy. A patient who received PBS-subsidised infliximab, vedolizumab or adalimumab treatment prior to 1 December 2016 is considered to be in their first cycle as of 1 December 2016. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised infliximab, vedolizumab or adalimumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised infliximab, vedolizumab or adalimumab treatment in the most recent cycle to the date of the first application for initial treatment with infliximab, vedolizumab or adalimumab under the new treatment cycle. A patient who has failed fewer than 3 trials of either infliximab, vedolizumab or adalimumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

(1) How to prescribe PBS-subsidised treatment with infliximab, vedolizumab and adalimumab after therapy after 1 December 2016 .

(a) Initial treatment. Applications for initial treatment should be made where:

(i) an adult patient has received no prior PBS-subsidised treatment with infliximab, vedolizumab or adalimumab in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) an adult patient has received prior PBS-subsidised (initial or continuing) infliximab, vedolizumab or adalimumab therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) an adult patient wishes to re-commence treatment with infliximab, vedolizumab or adalimumab following a break in PBS-subsidised therapy with the same agent (Initial 2).

Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab , 14 weeks of therapy for infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab, and this assessment must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is provided to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with infliximab, vedolizumab or adalimumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment. Assessments of response to a course of PBS-subsidised therapy must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate infliximab, vedolizumab or adalimumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy. A patient may trial an alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with infliximab, vedolizumab or adalimumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate infliximab, vedolizumab or adalimumab therapy should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Mayo clinic score or partial Mayo clinic score submitted with the first authority application for infliximab, vedolizumab or adalimumab. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is provided within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response,

the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised infliximab, vedolizumab or adalimumab therapy of at least 5 years, must requalify for initial treatment with respect to the scores of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the Mayo score is measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.
A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 December 2016 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to infliximab and adalimumab only.A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time. Infliximab and adalimumab are PBS-subsidised for moderate to severe disease while only infliximab is PBS-subsidised for acute severe disease.From 1 June 2017, under the PBS, all will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent.Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 June 2017 is considered to be in their first cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 June 2017.(a) Initial treatment.Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient has received prior PBS-subsidised (initial or continuing) treatment with a TNF-alfa antagonist and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping treatment' below]; or (iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2). Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted tothe Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply. Assessments of response to a course of PBS-subsidised treatment must be submitted the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.(2) Swapping treatment. Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.A patient may trial an alternate agent at any time,

regardless of whether they are receiving treatment (initial or continuing) with infliximab or adalimumab at the time of the application. However, a patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PUCAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the PUCAI score is measured.(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab. A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 June 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction.A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1)

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

**Treatment criteria:**

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

Applications for authorisation of initial treatment must be in writing and must include:(a) two completed authority prescription forms; and(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and(iii) the signed patient acknowledgement or guardian acknowledgement.

For patients weighing 40 kg or greater, a maximum quantity and number of repeats to provide for an initial 16 weeks course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 will be authorised.

For patients weighing less than 40 kg, a maximum quantity and number of repeats to provide for an initial 16 weeks of this drug consisting of a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14 will be authorised.

Two completed authority prescriptions must be submitted with every initial application for this drug.For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription must be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 1 month old at the time of application.

Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 within the first 12 weeks of receiving this drug for ulcerative colitis, or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or have failed to maintain a PUCAI score less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The patient or guardian (required if patient is aged 6 to 17 years) must have signed a patient acknowledgement indicating that he or she understands and acknowledges that the PBS-subsidised treatment will cease if he or she does not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

**Note** At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Change or Re-commencement of treatment after a break of less than 5 years in therapy (Initial 2)

**Treatment criteria:**

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

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with adalimumab, infliximab or vedolizumab for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with adalimumab or infliximab for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have failed PBS-subsidised treatment with adalimumab for this condition in the current treatment cycle; OR
- Patient must not have failed PBS-subsidised treatment with adalimumab for this condition in the current treatment cycle more than once if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug.

Applications for authorisation of initial treatment must be in writing and must include:

(a) two completed authority prescription forms; and(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

Two completed authority prescriptions must be submitted with every initial application for this drug.For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription must be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Note** At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

**Note** No applications for increased repeats will be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply for Initial 1 and Initial 2

**Clinical criteria:**

- Patient must have received insufficient treatment with this drug under the Initial 1 (new patient or recommencement of treatment after more than 5 years break in therapy) restriction to complete 16 weeks of treatment; OR
- Patient must have received insufficient treatment with this drug under the Initial 2 (Change or Re-commencing of treatment after less than 5 years break in therapy) to complete 16 weeks of treatment.

**Population criteria:**

- Patient must be 6 years of age or older.

**Treatment criteria:**

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

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

| 10955N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| 10944B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL syringes**

| 10972L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 3989.10 | 38.80 | Humira [VE] |

**adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

| 11127P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges**

| 10945C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 3989.10 | 38.80 | Humira [VE] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of infliximab, vedolizumab and adalimumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either infliximab, vedolizumab or adalimumab at any one time. From 1 December 2016, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial each of PBS-subsidised infliximab, vedolizumab or adalimumab without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with infliximab, vedolizumab or adalimumab while they continue to show a response to therapy. A patient who received PBS-subsidised infliximab, vedolizumab or adalimumab treatment prior to 1 December 2016 is considered to be in their first cycle as of 1 December 2016. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised infliximab, vedolizumab or adalimumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised infliximab, vedolizumab or adalimumab treatment in the most recent cycle to the date of the first application for initial treatment with infliximab, vedolizumab or adalimumab under the new treatment cycle. A patient who has failed fewer than 3 trials of either infliximab, vedolizumab or adalimumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

(1) How to prescribe PBS-subsidised treatment with infliximab, vedolizumab and adalimumab after therapy after 1 December 2016 .
(a) Initial treatment. Applications for initial treatment should be made where:
(i) an adult patient has received no prior PBS-subsidised treatment with infliximab, vedolizumab or adalimumab in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) an adult patient has received prior PBS-subsidised (initial or continuing) infliximab, vedolizumab or adalimumab therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) an adult patient wishes to re-commence treatment with infliximab, vedolizumab or adalimumab following a break in PBS-subsidised therapy with the same agent (Initial 2).
Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab , 14 weeks of therapy for infliximab and vedolizumab.
A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab, and this assessment must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is provided to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with infliximab, vedolizumab or adalimumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment. Assessments of response to a course of PBS-subsidised therapy must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate infliximab, vedolizumab or adalimumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy. A patient may trial an alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with infliximab, vedolizumab or adalimumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate infliximab, vedolizumab or adalimumab therapy should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Mayo clinic score or partial Mayo clinic score submitted with the first authority application for infliximab, vedolizumab or adalimumab. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is provided within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised infliximab, vedolizumab or adalimumab therapy of at least 5 years, must requalify for initial treatment with respect to the scores of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the Mayo score is measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.
A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 December 2016 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to infliximab and adalimumab only.A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time. Infliximab and adalimumab are PBS-subsidised for moderate to severe disease while only infliximab is PBS-subsidised for acute severe disease.From 1 June 2017, under the PBS, all will be able to commence a treatment cycle

where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent.Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 June 2017 is considered to be in their first cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 June 2017.(a) Initial treatment.Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient has received prior PBS-subsidised (initial or continuing) treatment with a TNF-alfa antagonist and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping treatment' below]; or (iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2). Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted tothe Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply. Assessments of response to a course of PBS-subsidised treatment must be submitted the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.(2) Swapping treatment. Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.A patient may trial an alternate agent at any time, regardless of whether they are receiving treatment (initial or continuing) with infliximab or adalimumab at the time of the application. However, a patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PUCAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the PUCAI score is measured.(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab. A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 June 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction.A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction. 'Grandfather'

arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

**Treatment criteria:**

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

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

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

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

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

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** No applications for increased repeats will be authorised.

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial 3 (Grandfathered patient)

**Clinical criteria:**

- Patient must have a documented history of moderate to severe ulcerative colitis, **AND**
- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2016, **AND**
- Patient must be receiving treatment with this drug at the time of application, **AND**
- Patient must have a Mayo score greater than or equal to 6 prior to commencing treatment with this drug; OR
- Patient must have a partial Mayo score is greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing treatment with this drug; OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 prior to commencing treatment with this drug, if aged 6 to 17 years; OR
- Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced treatment with this drug where a Mayo clinic, partial Mayo clinic or PUCAI baseline assessment is not available, if aged 6 to 17 years, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

**Treatment criteria:**

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

- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Applications for authorisation of initial treatment must be in writing and must include: (a) a completed authority prescription form; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current and baseline Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheets including the dates of assessment of the patient's condition; and (ii) the date of commencement of this drug; and (iii) the signed patient or guardian acknowledgement

The current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment must be no more than 1 month old at the time of application. The baseline assessment must be from immediately prior to commencing treatment with this drug. Where a baseline assessment is not available the prescriber must contact the Department of Human Services to discuss.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

**Note** The patient or guardian (required if patient is aged 6 to 17 years) must have signed a patient acknowledgement indicating that he or she understands and acknowledges that the PBS-subsidised treatment will cease if he or she does not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

**Note** No applications for increased repeats will be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply for Continuing treatment and Initial 3 (Grandfathered patients)

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR
- Patient must have received insufficient treatment with this drug to complete 24 weeks of treatment under the Initial 3 (Grandfathered patients).

**Population criteria:**

- Patient must be 6 years of age or older.

**Treatment criteria:**

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

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10961X | 1 | 5 | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10960W | 1 | 5 | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11121H | 1 | 5 | .. | 1401.83 | 38.80 | Humira [VE] |

## ▪ ADALIMUMAB

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major

joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose

based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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

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

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) a completed authority prescription form and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who

has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the

required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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

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

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

9099X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

8737W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1401.83 | 38.80 | Humira [VE] |

## ▪ ADALIMUMAB

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

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

**Authority required**

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or secukinumab in this treatment cycle, **AND**

- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

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

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be eligible to receive further bDMARD therapy.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis.
Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.
Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised bDMARD therapy
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Grandfather patients - secukinumab only.
For patients who commenced treatment with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction
(c) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

**Clinical criteria:**

- Patient must have active, or a documented history of active, ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

9103D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

9077R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1401.83 | 38.80 | Humira [VE] |

## ▪ ADALIMUMAB

**Note** No applications for increased maximum quantities will be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab,or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).

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

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.

For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate

adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.
A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.
(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.
A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment (new patient - initial 1)

**Treatment criteria:**

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

**Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, **AND**
- Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR
- Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting the Department of Human Services.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial 16 week course of this drug will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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

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**Authority required**

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

**Treatment criteria:**

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

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity and number of repeats to provide for an initial 16 week course of this drug will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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

**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply

**Treatment criteria:**

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

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the initial dose (i.e. the initial infusion regimen at weeks 0 and 2); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 2 doses (new patients) or 5 repeats (Continuing treatment).

**Population criteria:**

- Patient must be aged 18 years or older.

Authority approval for sufficient therapy to complete a maximum of 2 initial doses or 5 repeats may be requested by telephone by contacting the Department of Human Services

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

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

9190Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| 9188N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL syringes**

| 9186L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 3989.10 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges**

| 9187M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 3989.10 | 38.80 | Humira [VE] |

## ▪ ADALIMUMAB

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

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe active psoriatic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.
Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.
Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.
Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.
Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.
Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.
Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
Grandfather patients - ustekinumab and secukinumab only.
For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the

relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

9101B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

9033K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1401.83 | 38.80 | Humira [VE] |

## ▪ ADALIMUMAB

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.
Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.
Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological

agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

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

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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

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

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

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

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

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

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

9428F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

9427E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1401.83 | 38.80 | Humira [VE] |

## ▪ ADALIMUMAB

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.
Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.
Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.
Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.
Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Application for approval for initial treatment.
Applications for a course of initial treatment should be made in the following situations:
(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or
(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of

treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.
Grandfather patients (ixekizumab only).
Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Application for continuing treatment.
Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.
For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
(4) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.
(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii)

cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**

- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**

- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years ) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

9426D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 4 | .. | 1401.83 | 38.80 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

9425C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 4 | .. | 1401.83 | 38.80 | Humira [VE] |

## ▪ CERTOLIZUMAB PEGOL

**Note** Authority approval for sufficient therapy to complete a maximum of 18-20 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 18-20 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen, **AND**
- The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

10892G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 1202.08 | 38.80 | Cimzia [UC] |

## ▪ CERTOLIZUMAB PEGOL

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

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

**Note** Authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

**Clinical criteria:**

- Patient must have active, or a documented history of active, ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 18 to 20 weeks treatment; OR

- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 18 to 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

10897M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 1202.08 | 38.80 | Cimzia [UC] |

## ▪ CERTOLIZUMAB PEGOL

**Note** Authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 18 to 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

10896L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 1202.08 | 38.80 | Cimzia [UC] |

## ▪ CERTOLIZUMAB PEGOL

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

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

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

3425G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
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| 1 | 5 | .. | 1202.08 | 38.80 | Cimzia [UC] |

## ▪ CERTOLIZUMAB PEGOL

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab,

etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major

joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have not failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times., **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction..

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of

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

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction..

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) a completed authority prescription form and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

10905Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | .. | .. | *3549.97 | 38.80 | Cimzia [UC] |

## ▪ CERTOLIZUMAB PEGOL

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

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

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

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

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years

may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised bDMARD therapy
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Grandfather patients - secukinumab only.
For patients who commenced treatment with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction
(c) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

10137M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1202.08 | 38.80 | Cimzia [UC] |

## ▪ CERTOLIZUMAB PEGOL

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

**Authority required**

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or secukinumab in this treatment cycle, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

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

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 18 to 20 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be eligible to receive further bDMARD therapy.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 18 to 20 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis.
Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.
Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised bDMARD therapy

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Grandfather patients - secukinumab only.
For patients who commenced treatment with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction
(c) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

| 10904X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | .. | .. | *3549.97 | 38.80 | Cimzia [UC] |

## ▪ CERTOLIZUMAB PEGOL

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

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

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was

granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.
Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.
Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.
Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
Grandfather patients - ustekinumab and secukinumab only.
For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

10238W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1202.08 | 38.80 | Cimzia [UC] |

## ▪ CERTOLIZUMAB PEGOL

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe active psoriatic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response

assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

10909E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | .. | .. | *3549.97 | 38.80 | Cimzia [UC] |

## ▪ ETANERCEPT

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

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

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab,

etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major

joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9090K | 1 | 5 | .. | 1049.30 | 38.80 | [a] Brenzys [MK] | [a] Enbrel [PF] |

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9460X | 1 | 5 | .. | 1049.30 | 38.80 | [a] Brenzys [MK] | [a] Enbrel [PF] |

## ▪ ETANERCEPT

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have demonstrated an adequate response to treatment with etanercept, **AND**
- Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient etanercept therapy under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

| 3449M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 1049.30 | 38.80 | Enbrel [PF] |

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

| 3450N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 1049.30 | 38.80 | Enbrel [PF] |

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

| 3448L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1049.31 | 38.80 | Enbrel [PF] |

## ▪ ETANERCEPT

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**

- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

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

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding

rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

8638P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *1049.31 | 38.80 | Enbrel [PF] |

## ▪ ETANERCEPT

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product

Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most

recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

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

If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the

dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9089J | 1 | 3 | .. | 1049.30 | 38.80 | [a] Brenzys [MK] | [a] Enbrel [PF] |

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9459W | 1 | 3 | .. | 1049.30 | 38.80 | [a] Brenzys [MK] | [a] Enbrel [PF] |

## ▪ ETANERCEPT

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR
- Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately

prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**

- Patient must not have failed PBS-subsidised therapy with etanercept for this condition in the current treatment cycle,

**AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient etanercept therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient etanercept therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

| 3446J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 1049.30 | 38.80 | Enbrel [PF] |

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

| 3447K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 1049.30 | 38.80 | Enbrel [PF] |

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

| 3445H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 3 | .. | *1049.31 | 38.80 | Enbrel [PF] |

## ▪ ETANERCEPT

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

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis.
Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.
Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years

may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised bDMARD therapy
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Grandfather patients - secukinumab only.
For patients who commenced treatment with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction
(c) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

9086F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 1049.30 | 38.80 | [a] Brenzys [MK] | [a] Enbrel [PF] |

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

9456Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 1049.30 | 38.80 | [a] Brenzys [MK] | [a] Enbrel [PF] |

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

8779C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *1049.31 | 38.80 | Enbrel [PF] |

## ▪ ETANERCEPT

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated

kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD

without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

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

If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
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**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

8637N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | .. | *1049.31 | 38.80 | Enbrel [PF] |

## ▪ ETANERCEPT

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

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

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

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

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9088H | 1 | 5 | .. | 1049.30 | 38.80 | [a] Brenzys [MK] | [a] Enbrel [PF] |

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9458T | 1 | 5 | .. | 1049.30 | 38.80 | [a] Brenzys [MK] | [a] Enbrel [PF] |

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9036N | 2 | 5 | .. | *1049.31 | 38.80 | Enbrel [PF] |

## ▪ ETANERCEPT

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

**Authority required**

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or secukinumab in this treatment cycle, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

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

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be eligible to receive further bDMARD therapy.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis.
Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.
Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised bDMARD therapy
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Grandfather patients - secukinumab only.
For patients who commenced treatment with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction
(c) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

**Clinical criteria:**

- Patient must have active, or a documented history of active, ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

9085E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 1049.30 | 38.80 | [a] Brenzys [MK] | [a] Enbrel [PF] |

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

9455P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 1049.30 | 38.80 | [a] Brenzys [MK] | [a] Enbrel [PF] |

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

8778B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | .. | *1049.31 | 38.80 | Enbrel [PF] |

## ▪ ETANERCEPT

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

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

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

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

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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

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

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

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

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a

response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

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

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

9431J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 1049.30 | 38.80 | [a] Brenzys [MK] | [a] Enbrel [PF] |

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

9462B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 1049.30 | 38.80 | [a] Brenzys [MK] | [a] Enbrel [PF] |

## ▪ ETANERCEPT

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

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

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe active psoriatic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be

deemed to have failed to respond to treatment with that biological agent.
Grandfather patients - ustekinumab and secukinumab only.
For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

| 9087G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 1049.30 | 38.80 | [a] Brenzys [MK] | [a] Enbrel [PF] |

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

| 9457R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 1049.30 | 38.80 | [a] Brenzys [MK] | [a] Enbrel [PF] |

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

| 9035M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 3 | .. | *1049.31 | 38.80 | Enbrel [PF] |

## ▪ ETANERCEPT

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.
Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.
Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.
Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.
Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Application for approval for initial treatment.
Applications for a course of initial treatment should be made in the following situations:
(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or
(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.
Grandfather patients (ixekizumab only).
Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017

may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Application for continuing treatment.
Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.
For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
(4) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.
(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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

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

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

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

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

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

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

9429G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *1049.31 | 38.80 | Enbrel [PF] |

## ▪ ETANERCEPT

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

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

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment (whole body)

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have lesions present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with etanercept for this condition; OR
- Patient must not have received any PBS-subsidised treatment with etanercept for this condition for at least 12 months, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the parent or authorised guardian signed patient and prescriber acknowledgements.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

**Note** Details of acceptable toxicities including severity, associated with phototherapy, methotrexate and acitretin, can be found on the Department of Human Services website at www.humanservices.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment or Re-treatment (Whole body) - balance of first supply

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have received insufficient therapy under the Initial treatment (whole body) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy under the Re-treatment (whole body) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment or Re-treatment (Whole body) - completion of course

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have received 16 weeks treatment under the Initial treatment (whole body) restriction for severe chronic plaque psoriasis; OR
- Patient must have received 16 weeks treatment under the Re-treatment (whole body) restriction for severe chronic plaque psoriasis, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, when compared with the pre-etanercept treatment baseline value.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of assessment of the patient's condition.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

A PASI assessment of the patient's response to the initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for a further 8 weeks of treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their initial 16 week treatment course to ensure continuity of treatment for those patients who meet the eligibility criterion for a further 8 weeks of PBS-subsidised etanercept treatment.

**Note** In circumstances where it is not possible to submit a response assessment after 12 weeks of treatment, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Re-treatment (Whole body)

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR

- The treatment must be in combination with methotrexate, **AND**
- Patient must have a documented history of severe chronic plaque psoriasis of the whole body, **AND**
- Patient must have received prior PBS-subsidised treatment with etanercept for this condition in the past 12 months, **AND**
- Patient must have demonstrated a response to etanercept and experienced a disease flare; OR
- Patient must not have failed more than once to achieve an adequate response with etanercept, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

A patient is eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior etanercept treatment, including date ceased.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment (Face, hand, foot)

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with etanercept for this condition; OR
- Patient must not have received any PBS-subsidised treatment with etanercept for this condition for at least 12 months, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or (iii)acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and face, hand, foot area diagrams including the dates of assessment of the patient's condition

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the parent or authorised guardian signed patient and prescriber acknowledgements.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

**Note** Details of acceptable toxicities including severity, associated with phototherapy, methotrexate and acitretin, can be found on the Department of Human Services website at www.humanservices.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment of Re-treatment (Face, hand, foot) - balance of first supply

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**

- Patient must have received insufficient therapy under the Initial treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy under the Re-treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment or Re-treatment (Face, hand, foot) - completion of course

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have received 16 weeks treatment under the Initial treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis; OR
- Patient must have received 16 weeks treatment under the Re-treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of assessment of the patient's condition.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

A PASI assessment of the patient's response to the initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for a further 8 weeks of treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their initial 16 week treatment course to ensure continuity of treatment for those patients who meet the eligibility criterion for a further 8 weeks of PBS-subsidised etanercept treatment.

**Note** In circumstances where it is not possible to submit a response assessment after 12 weeks of treatment, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Re-treatment (Face, hand, foot)

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received prior PBS-subsidised treatment with etanercept for this condition in the past 12 months, **AND**
- Patient must have demonstrated a response to etanercept and experienced a disease flare; OR
- Patient must not have failed more than once to achieve an adequate response with etanercept, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

A patient is eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the 3 subscores are rated severe to very severe; or

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

The authority application must be made in writing and must include :

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area digrams including the dates of assessment of the patient's condition; and

(ii) details of prior etanercept treatment, including date ceased.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services

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**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

| 1963H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 1049.30 | 38.80 | Enbrel [PF] |

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

| 1964J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 1049.30 | 38.80 | Enbrel [PF] |

## ▪ ETANERCEPT

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

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

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

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

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the

Department of Human Services on 1800 700 270 to discuss.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Application for continuing treatment.
Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.
For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
(4) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.
(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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

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

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy,

will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years ) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

9091L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 1049.30 | 38.80 | [a] Brenzys [MK] | [a] Enbrel [PF] |

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

9461Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 1049.30 | 38.80 | [a] Brenzys [MK] | [a] Enbrel [PF] |

## ▪ ETANERCEPT

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment (whole body)

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have lesions present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with etanercept for this condition; OR
- Patient must not have received any PBS-subsidised treatment with etanercept for this condition for at least 12 months, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the parent or authorised guardian signed patient and prescriber acknowledgements.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

**Note** Details of acceptable toxicities including severity, associated with phototherapy, methotrexate and acitretin, can be found on the Department of Human Services website at www.humanservices.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment or Re-treatment (Whole body) - balance of first supply

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have received insufficient therapy under the Initial treatment (whole body) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy under the Re-treatment (whole body) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment or Re-treatment (Whole body) - completion of course

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have received 16 weeks treatment under the Initial treatment (whole body) restriction for severe chronic plaque psoriasis; OR
- Patient must have received 16 weeks treatment under the Re-treatment (whole body) restriction for severe chronic plaque psoriasis, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, when compared with the pre-etanercept treatment baseline value.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of assessment of the patient's condition.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

A PASI assessment of the patient's response to the initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for a further 8 weeks of treatment, must be submitted no later than 1 month from the date of completion

of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their initial 16 week treatment course to ensure continuity of treatment for those patients who meet the eligibility criterion for a further 8 weeks of PBS-subsidised etanercept treatment.

**Note** In circumstances where it is not possible to submit a response assessment after 12 weeks of treatment, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Re-treatment (Whole body)

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have a documented history of severe chronic plaque psoriasis of the whole body, **AND**
- Patient must have received prior PBS-subsidised treatment with etanercept for this condition in the past 12 months, **AND**
- Patient must have demonstrated a response to etanercept and experienced a disease flare; OR
- Patient must not have failed more than once to achieve an adequate response with etanercept, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

A patient is eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior etanercept treatment, including date ceased.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment (Face, hand, foot)

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with etanercept for this condition; OR
- Patient must not have received any PBS-subsidised treatment with etanercept for this condition for at least 12 months, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or (iii)acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and face, hand, foot area diagrams including the dates of assessment of the patient's condition

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the parent or authorised guardian signed patient and prescriber acknowledgements.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

**Note** Details of acceptable toxicities including severity, associated with phototherapy, methotrexate and acitretin, can be found on the Department of Human Services website at www.humanservices.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment of Re-treatment (Face, hand, foot) - balance of first supply

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have received insufficient therapy under the Initial treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy under the Re-treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment or Re-treatment (Face, hand, foot) - completion of course

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these

timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have received 16 weeks treatment under the Initial treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis; OR
- Patient must have received 16 weeks treatment under the Re-treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of assessment of the patient's condition.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

A PASI assessment of the patient's response to the initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for a further 8 weeks of treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their initial 16 week treatment course to ensure continuity of treatment for those patients who meet the eligibility criterion for a further 8 weeks of PBS-subsidised etanercept treatment.

**Note** In circumstances where it is not possible to submit a response assessment after 12 weeks of treatment, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Re-treatment (Face, hand, foot)

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received prior PBS-subsidised treatment with etanercept for this condition in the past 12 months, **AND**
- Patient must have demonstrated a response to etanercept and experienced a disease flare; OR
- Patient must not have failed more than once to achieve an adequate response with etanercept, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

A patient is eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the 3 subscores are rated severe to very severe; or

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

The authority application must be made in writing and must include :

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area digrams including the dates of assessment of the patient's condition; and

(ii) details of prior etanercept treatment, including date ceased.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

1954W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | .. | *1049.31 | 38.80 | Enbrel [PF] |

## ▪ ETANERCEPT

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.
Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.
Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.
Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.
Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Application for approval for initial treatment.
Applications for a course of initial treatment should be made in the following situations:
(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or
(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.
Grandfather patients (ixekizumab only).
Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Application for continuing treatment.
Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.
For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
(4) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.
(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years ) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
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**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

9037P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | .. | *1049.31 | 38.80 | Enbrel [PF] |

## ▪ GOLIMUMAB

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with golimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with golimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with golimumab.

If a patient fails to demonstrate a response to treatment with golimumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a

disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3428K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1357.17 | 38.80 | Simponi [JC] |

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3429L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1357.17 | 38.80 | Simponi [JC] |

## ▪ GOLIMUMAB

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be

submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) a completed authority prescription form and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please

contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised

TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3426H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1357.17 | 38.80 | Simponi [JC] |

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3427J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1357.17 | 38.80 | Simponi [JC] |

## ▪ GOLIMUMAB

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

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**

- Patient must have demonstrated an adequate response to treatment with this drug.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis.

Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

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

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

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

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

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

(1) How to prescribe PBS-subsidised bDMARD therapy

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Grandfather patients - secukinumab only.

For patients who commenced treatment with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction

(c) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24

weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3436W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1357.17 | 38.80 | Simponi [JC] |

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

| 3437X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 1357.17 | 38.80 | Simponi [JC] |

## ▪ GOLIMUMAB

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

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

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

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

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new

Cycle.
Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.
Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.
Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
Grandfather patients - ustekinumab and secukinumab only.
For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of

at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3432P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1357.17 | 38.80 | Simponi [JC] |

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3433Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1357.17 | 38.80 | Simponi [JC] |

## ▪ GOLIMUMAB

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

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

**Authority required**

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or secukinumab in this treatment cycle, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

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

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be eligible to receive further bDMARD therapy.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis.

Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

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

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

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

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

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

(1) How to prescribe PBS-subsidised bDMARD therapy

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Grandfather patients - secukinumab only.

For patients who commenced treatment with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction

(c) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID

therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

**Clinical criteria:**

- Patient must have active, or a documented history of active, ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3434R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1357.17 | 38.80 | Simponi [JC] |

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3435T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1357.17 | 38.80 | Simponi [JC] |

## ▪ GOLIMUMAB

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

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe active psoriatic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be

deemed to have failed to respond to treatment with that biological agent.
Grandfather patients - ustekinumab and secukinumab only.
For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

| 3430M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 1357.17 | 38.80 | Simponi [JC] |

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

| 3431N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 1357.17 | 38.80 | Simponi [JC] |

*Interleukin inhibitors*

## ▪ DACLIZUMAB

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

**Authority required**
Multiple sclerosis
Treatment Phase: Initial treatment
**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.
Patients should undergo monthly liver function testing while being treated with this drug.

**Authority required**
Multiple sclerosis
Treatment Phase: Continuing treatment
**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Treatment criteria:**

- Must be treated by a neurologist.

Patients should undergo monthly liver function testing while being treated with this drug.

**Authority required**
Multiple sclerosis
Treatment Phase: Grandfathering treatment
**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years prior to initiation of this drug, **AND**
- Patient must have received treatment with this drug for this condition prior to 1 May 2017, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support), **AND**

- The treatment must not exceed 24 weeks under this restriction.

**Treatment criteria:**

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Patients should undergo monthly liver function testing while being treated with this drug.

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

**daclizumab 150 mg/mL injection, 1 mL injection device**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11101G | 1 | 5 | .. | 2232.85 | 38.80 | Zinbryta [BD] |

## ▪ IXEKIZUMAB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.
Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.
Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.
Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.
Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Application for approval for initial treatment.
Applications for a course of initial treatment should be made in the following situations:
(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or
(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.
Grandfather patients (ixekizumab only).
Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Application for continuing treatment.
Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.
For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
(4) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.
(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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

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

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 3, Whole body (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have been receiving treatment with this drug for this condition prior to 1 February 2017, **AND**
- Patient must have had a Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing treatment with this drug, **AND**
- Patient must have demonstrated a response to treatment as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with this drug (whole body), **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug) and the most recent PASI assessment; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

The most recent PASI assessment must be no more than 1 month old at the time of application.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

**Note** A PASI assessment of the patient's response to this initial PBS-subsidised course of therapy must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

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

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment

Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 3, Face, hand, foot (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have been receiving treatment with this drug for this condition prior to 1 February 2017, **AND**
- Patient must have had disease, prior to treatment with this drug, classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling were rated as severe or very severe; or (ii) the skin area affected was 30% or more of the face, palm of a hand or sole of a foot, **AND**
- Patient must have demonstrated a response to treatment as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with this drug (face, hand, foot), **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug) and the most recent PASI assessment; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The PASI assessment must be performed on the same affected area as assessed at baseline or prior to initiation of treatment with this drug.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

**Note** A PASI assessment of the patient's response to this initial PBS-subsidised course of therapy must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

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

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 3, Whole body or Face, hand, foot (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) or Continuing treatment, Whole body or Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 3, Whole body (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 3, Face, hand, foot (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**ixekizumab 80 mg/mL injection, 2 x 1 mL injection devices**

11033Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 3409.52 | 38.80 | Taltz [LY] |

## ▪ IXEKIZUMAB

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

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

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological

agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.
(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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

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

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years ) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### ixekizumab 80 mg/mL injection, 2 x 1 mL injection devices

11032P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 3409.52 | 38.80 | Taltz [LY] |

## ▪ SECUKINUMAB

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

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

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment after a break of less than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have active, or had a documented history of active ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks of treatment, **AND**

- The treatment must provide no more than the balance of up to 16 weeks treatment available under the initial 1 or 2 restrictions.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

**secukinumab 150 mg/mL injection, 1 mL injection device**

10893H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 804.59 | 38.80 | Cosentyx [NV] |

## ▪ SECUKINUMAB

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

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

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencing treatment after a break of less than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete maximum of 16 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencing treatment after a break of less than 5 years) restriction to complete maximum of 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**secukinumab 150 mg/mL injection, 1 mL injection device**

10898N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 804.59 | 38.80 | Cosentyx [NV] |

## ▪ SECUKINUMAB

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

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

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencing treatment after a break of less than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete maximum of 16 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencing treatment after a break of less than 5 years) restriction to complete maximum of 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**secukinumab 150 mg/mL injection, 2 x 1 mL injection devices**

10901R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 1586.28 | 38.80 | Cosentyx [NV] |

## ▪ SECUKINUMAB

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.
Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.
Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.
Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.
Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Application for approval for initial treatment.
Applications for a course of initial treatment should be made in the following situations:
(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or
(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.
Grandfather patients (ixekizumab only).
Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the

Department of Human Services on 1800 700 270 to discuss.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Application for continuing treatment.
Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.
For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
(4) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.
(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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

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

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years ) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

### secukinumab 150 mg/mL injection, 2 x 1 mL injection devices

10494H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 1586.28 | 38.80 | Cosentyx [NV] |

## ▪ SECUKINUMAB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

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

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**Authority required**

Active ankylosing spondylitis

Treatment Phase: Initial treatment – initial 1 (new patients or patients recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or secukinumab in this treatment cycle, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

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

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencing treatment after a break of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**

- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be eligible to receive further bDMARD therapy.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis.
Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.
Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised bDMARD therapy
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Grandfather patients - secukinumab only.
For patients who commenced treatment with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction
(c) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24

weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**secukinumab 150 mg/mL injection, 1 mL injection device**

10890E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | .. | .. | *3170.59 | 38.80 | Cosentyx [NV] |

## ▪ SECUKINUMAB

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

**Authority required**

Severe active psoriatic arthritis

Treatment Phase: Initial 3 - grandfather treatment

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received non-PBS treatment with this drug for this condition prior to 1 October 2016, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to response, or to have failed to sustain a response to treatment with this drug.

Patients may qualify for PBS-subsidised treatment under this restriction once only. Further applications for treatment with this drug will be assessed under the continuing treatment restriction.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement; and

(4) the date of commencement of this drug; and

(5) results of the baseline patient assessment prior to commencing treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

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

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5

years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active psoriatic arthritis

Treatment Phase: Initial 3 (grandfather treatment) or Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 3 (grandfather patients) restriction to complete maximum of 24 weeks treatment, **AND**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**secukinumab 150 mg/mL injection, 1 mL injection device**

10895K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 804.59 | 38.80 | Cosentyx [NV] |

## ▪ SECUKINUMAB

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

**Authority required**

Severe active psoriatic arthritis

Treatment Phase: Initial 3 - grandfather treatment

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received non-PBS treatment with this drug for this condition prior to 1 October 2016, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**

- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to response, or to have failed to sustain a response to treatment with this drug.

Patients may qualify for PBS-subsidised treatment under this restriction once only. Further applications for treatment with this drug will be assessed under the continuing treatment restriction.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement; and

(4) the date of commencement of this drug; and

(5) results of the baseline patient assessment prior to commencing treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

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

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access

the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active psoriatic arthritis

Treatment Phase: Initial 3 (grandfather treatment) or Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 3 (grandfather patients) restriction to complete maximum of 24 weeks treatment, **AND**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**secukinumab 150 mg/mL injection, 2 x 1 mL injection devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10899P | 1 | 5 | .. | 1586.28 | 38.80 | Cosentyx [NV] |

## ▪ SECUKINUMAB

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

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

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe active psoriatic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: initial treatment - Initial 2 (change or recommencing treatment after a break of less than 5 years )

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.
Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.
Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.
Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.
Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.
Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.
Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
Grandfather patients - ustekinumab and secukinumab only.
For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe this drug should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**secukinumab 150 mg/mL injection, 2 x 1 mL injection devices**

10894J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | .. | .. | *6191.63 | 38.80 | Cosentyx [NV] |

## ▪ SECUKINUMAB

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

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

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe active psoriatic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: initial treatment - Initial 2 (change or recommencing treatment after a break of less than 5 years )

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.
Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe this drug should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**secukinumab 150 mg/mL injection, 1 mL injection device**

10900Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | .. | .. | *3170.59 | 38.80 | Cosentyx [NV] |

## ▪ SECUKINUMAB

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.
Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.
Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.
Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.
Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Application for approval for initial treatment.
Applications for a course of initial treatment should be made in the following situations:
(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or
(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.
Grandfather patients (ixekizumab only).
Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Application for continuing treatment.
Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.
For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
(4) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.
(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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

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

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

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

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment

course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

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

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**secukinumab 150 mg/mL injection, 2 x 1 mL injection devices**

10425Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1586.28 | 38.80 | Cosentyx [NV] |

## ▪ SECUKINUMAB

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

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

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 3 (grandfather treatment)

**Clinical criteria:**

- Patient must have confirmed ankylosing spondylitis, defined radiographically (plain X-ray) of Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, with the diagnosis confirmed by a rheumatologist, **AND**
- Patient must have been receiving treatment with this drug for this condition prior to 1 October 2016, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The baseline BASDAI assessment must be from immediately prior to commencing treatment with this drug. The patient's current BASDAI assessment and ESR and/or CRP measurements must be no more than 1 month old at the time of application. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form; and

(c) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(d) a completed BASDAI Assessment Form; and

(e) a signed patient acknowledgment form;

(f) the date commencement of this drug;

(g) results of the baseline BASDAI assessment prior to commencing treatment with this drug.

Patients may qualify for PBS-subsidised treatment under this restriction once only. Further applications for treatment with this drug will be assessed under the continuing treatment restriction.

**Note** The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis.

Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

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

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

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

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

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

(1) How to prescribe PBS-subsidised bDMARD therapy

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Grandfather patients - secukinumab only.

For patients who commenced treatment with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction

(c) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 3 or Continuing treatment – balance of supply

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the initial 3 treatment restriction to complete 24 weeks of treatment, **AND**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**secukinumab 150 mg/mL injection, 1 mL injection device**

10906B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 804.59 | 38.80 | Cosentyx [NV] |

## ▪ SECUKINUMAB

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

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

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

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

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not

possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
(4) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.
(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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

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

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**secukinumab 150 mg/mL injection, 2 x 1 mL injection devices**

10910F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | .. | .. | *6191.63 | 38.80 | Cosentyx [NV] |

## ▪ TOCILIZUMAB

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with tocilizumab, **AND**
- Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-

subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment

applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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

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

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment – balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

10954M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 953.23 | 38.80 | Actemra Subcutaneous Injection [RO] |

## ▪ TOCILIZUMAB

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

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

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with tocilizumab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:(1) completed authority prescription form(s); and(2) a completed Rheumatoid Arthritis initial PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement.If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or(b) at least 4 active joints from the following list of major joints:(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the

approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:(a) completed authority prescription form(s); and(b) a completed Rheumatoid Arthritis continuing PBS Authority Application - Supporting Information Form. Applications for a patient who has received PBS-subsidised treatment with tocilizumab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab. If a patient fails to demonstrate a response to a treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody

(rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

10951J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 953.23 | 38.80 | Actemra Subcutaneous Injection [RO] |

## ▪ USTEKINUMAB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

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

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

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

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

(4) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.
(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

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

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

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

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9305R | 1 | 1 | .. | 4346.86 | 38.80 | Stelara [JC] |

## ▪ USTEKINUMAB

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have been receiving treatment with this drug for this condition prior to 1 May 2016, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have demonstrated a response to treatment as specified in the criteria for continuing PBS-subsidised treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

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

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**

- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

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

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with

that specific agent (Initial 1 or Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.
Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
Grandfather patients - ustekinumab and secukinumab only.
For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) or Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

10767Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 4346.86 | 38.80 | Stelara [JC] |

## ▪ USTEKINUMAB

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have severe active psoriatic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

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

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment

course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an

alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more), Initial 2 (change or recommencement of treatment) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 28 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authority approval for sufficient therapy to complete the balance of supply should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

10774C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 4346.86 | 38.80 | Stelara [JC] |

## ▪ USTEKINUMAB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.
Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.
Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.
Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.
Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Application for approval for initial treatment.
Applications for a course of initial treatment should be made in the following situations:
(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or
(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.
Grandfather patients (ixekizumab only).
Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Application for continuing treatment.
Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are

eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.
For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
(4) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.
(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month

from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) restriction to complete 28 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

9304Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 4346.86 | 38.80 | Stelara [JC] |

## ▪ USTEKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab,or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).

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

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.

For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
(b) Continuing treatment.
Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.
A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.
(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.
A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment (new patient - initial 1)

**Treatment criteria:**

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

**Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug, **AND**
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, **AND**
- Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR
- Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

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

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

**Treatment criteria:**

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

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

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

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe Crohn disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

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

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

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

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

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

**Note** Increase in the maximum number of repeats of up to 2 may be authorised in patients whose dosing frequency is every 8 weeks.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
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Department of Human Services

Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe Crohn disease

Treatment Phase: Initial PBS-subsidised treatment (Grandfather)

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 September 2017, **AND**
- Patient must be receiving treatment with ustekinumab at the time of application, **AND**
- Patient must have had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with this drug; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

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

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease Grandfathered PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

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

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

**Note** No applications for increased maximum quantities will be authorised.

**Note** Increase in the maximum number of repeats of up to two may be authorised in patients whose dosing frequency is every 8 weeks.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
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Department of Human Services

Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply for Initial treatment, Continuing treatment or Grandfathered treatment

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 16 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Grandfathered treatment restriction to complete 24 weeks of treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

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

Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services

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

**Note** Applications for authority to prescribe may be made by phone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11178H | 2 | .. | .. | *8614.15 | 38.80 | Stelara [JC] |

*Calcineurin inhibitors*

## ▪ CYCLOSPORIN

**Caution** Careful monitoring of patients is mandatory.

**cyclosporin 100 mg/mL oral liquid, 50 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8661W | 2 | 3 | .. | *707.63 | 38.80 | Neoral [NV] |

**cyclosporin 10 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8657P | 2 | 3 | .. | *91.09 | 38.80 | Neoral 10 [NV] |

**cyclosporin 50 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8659R | 2 | 3 | .. | *155.25 | 38.80 | [a] Cyclosporin Sandoz [SZ] | [a] Neoral 50 [NV] |

**cyclosporin 25 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8658Q | 2 | 3 | .. | *80.37 | 38.80 | [a] Cyclosporin Sandoz [SZ] | [a] Neoral 25 [NV] |

**cyclosporin 100 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8660T | 2 | 3 | .. | *308.81 | 38.80 | [a] Cyclosporin Sandoz [SZ] | [a] Neoral 100 [NV] |

## ▪ TACROLIMUS

**Caution** Careful monitoring of patients is mandatory.

**tacrolimus 1 mg modified release capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5300Y | 1 | 3 | .. | 152.63 | 38.80 | [a] ADVAGRAF XL [LQ] | [a] Prograf XL [LL] |

**tacrolimus 2 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10871E | 1 | 3 | .. | 561.21 | 38.80 | Tacrolimus Sandoz [SZ] |

**tacrolimus 1 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8647D | 1 | 3 | .. | 248.95 | 38.80 | [a] Pacrolim [AF] | [a] Pharmacor Tacrolimus 1 [CR] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Prograf [LL]<br>[a] Tacrolimus Sandoz [SZ] | [a] TACROLIMUS APOTEX [TX] |

**tacrolimus 5 mg modified release capsule, 30**

| 5451X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 422.35 | 38.80 | [a] ADVAGRAF XL [LQ] | [a] Prograf XL [LL] |

**tacrolimus 5 mg capsule, 50**

| 8648E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 614.87 | 38.80 | [a] Pacrolim [AF]<br>[a] Prograf [LL]<br>[a] Tacrolimus Sandoz [SZ] | [a] Pharmacor Tacrolimus 5 [CR]<br>[a] TACROLIMUS APOTEX [TX] |

**tacrolimus 500 microgram modified release capsule, 30**

| 5299X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 51.43 | 38.80 | [a] ADVAGRAF XL [LQ] | [a] Prograf XL [LL] |

**tacrolimus 750 microgram capsule, 100**

| 10870D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 213.45 | 38.80 | Tacrolimus Sandoz [SZ] |

**tacrolimus 500 microgram capsule, 100**

| 8646C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 129.04 | 38.80 | [a] Pacrolim [AF]<br>[a] Prograf [LL]<br>[a] Tacrolimus Sandoz [SZ] | [a] Pharmacor Tacrolimus 0.5 [CR]<br>[a] TACROLIMUS APOTEX [TX] |

*Other immunosuppressants*

## ▪ AZATHIOPRINE

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

**azathioprine 25 mg tablet, 100**

| 2688L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 23.25 | 24.46 | [a] APO-Azathioprine [TX]<br>[a] Azathioprine Sandoz [SZ] | [a] Azathioprine GH [GQ]<br>[a] Imuran [AS] |

**azathioprine 50 mg tablet, 100**

| 2687K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 31.80 | 33.01 | [a] APO-Azathioprine [TX]<br>[a] Azapin [RW]<br>[a] Azathioprine GH [GQ]<br>[a] Imazan [ER]<br>[a] Thioprine 50 [AF] | [a] Azamun [ED]<br>[a] Azathioprine AN [EA]<br>[a] Azathioprine Sandoz [SZ]<br>[a] Imuran [AS] |

## ▪ METHOTREXATE

**methotrexate 10 mg tablet, 15**

| 2272N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 23.19 | 24.40 | Methoblastin [PF] |

**methotrexate 2.5 mg tablet, 30**

| 1622J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 16.92 | 18.13 | Methoblastin [PF] |

## ▪ METHOTREXATE

**Restricted benefit**
Patients requiring doses greater than 20 mg per week

**methotrexate 10 mg tablet, 50**

| 1623K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 51.41 | 38.80 | Methoblastin [PF] |

## ▪ PIRFENIDONE

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

**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 1 - new patient

**Clinical criteria:**

- The condition must be diagnosed through a multidisciplinary team, **AND**
- Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months, **AND**
- Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height, **AND**
- Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7, **AND**
- Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%, **AND**
- Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition.

**Treatment criteria:**

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

Patient must have not have an acute respiratory infection at the time of FVC testing.

Applications for authorisation of initial treatment must be in writing and must include:

a) a completed authority prescription form; and

b) a completed IPF Authority Application Supporting Information Form; and

c) a signed patient acknowledgement.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 2 - change or re-commencement of treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition.

**Treatment criteria:**

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition.

**Treatment criteria:**

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 3 - Grandfathering treatment

**Treatment criteria:**

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 July 2017, **AND**
- The condition must have been diagnosed through a multidisciplinary team, **AND**
- Patient must have had a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height at the time treatment with this drug for this condition was initiated, **AND**
- Patient must have had a forced expiratory volume in 1 second (FEV1)/FVC ratio greater than 0.7 at the time treatment with this drug for this condition was initiated, **AND**
- Patient must have had diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30% at the time treatment with this drug for this condition was initiated, **AND**
- Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition.

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

Patient must have not have an acute respiratory infection at the time of FVC testing.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria or change or recommencement of treatment criteria.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

Applications for authorisation of initial treatment must be in writing and must include:

a) a completed authority prescription form; and

b) a completed IPF Authority Application Supporting Information Form; and

c) a signed patient acknowledgement.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
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Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**pirfenidone 267 mg capsule, 270**

11136D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 3064.52 | 38.80 | Esbriet [RO] |

# MUSCULO-SKELETAL SYSTEM

## ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

### ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS

*Acetic acid derivatives and related substances*

### DICLOFENAC

**diclofenac sodium 100 mg suppository, 20**

1302M (NP) (MW)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | .. | *27.51 | 28.72 | Voltaren 100 [NV] |

**diclofenac sodium 100 mg suppository, 20**

5079H (DP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *27.51 | 28.72 | Voltaren 100 [NV] |

### DICLOFENAC

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**diclofenac sodium 50 mg enteric tablet, 50**

1300K (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 13.14 | 14.35 | [a] APO-Diclofenac [TX]<br>[a] Diclofenac Amneal [ED] | [a] Clonac 50 [RW]<br>[a] Diclofenac AN [EA] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Diclofenac Sandoz [SZ] | [a] Fenac [AF] |
| | | | [B]3.46 | 16.60 | 14.35 | [a] Voltaren 50 [NV] | |

**diclofenac sodium 25 mg enteric tablet, 50**

| 1299J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 3 | .. | *14.03 | 15.24 | [a] APO-Diclofenac [TX] | [a] Clonac 25 [RW] |
| | | | | | | [a] Diclofenac Amneal [ED] | [a] Diclofenac AN [EA] |
| | | | | | | [a] Diclofenac Sandoz [SZ] | [a] Fenac 25 [AF] |
| | | | [B]3.44 | *17.47 | 15.24 | [a] Voltaren 25 [NV] | |

## ▪ DICLOFENAC

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**diclofenac sodium 50 mg enteric tablet, 50**

| 5077F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 13.14 | 14.35 | [a] APO-Diclofenac [TX] | [a] Clonac 50 [RW] |
| | | | | | | [a] Diclofenac Amneal [ED] | [a] Diclofenac AN [EA] |
| | | | | | | [a] Diclofenac Sandoz [SZ] | [a] Fenac [AF] |
| | | | [B]3.46 | 16.60 | 14.35 | [a] Voltaren 50 [NV] | |

**diclofenac sodium 25 mg enteric tablet, 50**

| 5076E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 2 | .. | .. | *14.03 | 15.24 | [a] APO-Diclofenac [TX] | [a] Clonac 25 [RW] |
| | | | | | | [a] Diclofenac Amneal [ED] | [a] Diclofenac AN [EA] |
| | | | | | | [a] Diclofenac Sandoz [SZ] | [a] Fenac 25 [AF] |
| | | | [B]3.44 | *17.47 | 15.24 | [a] Voltaren 25 [NV] | |

## ▪ INDOMETHACIN

**indomethacin 100 mg suppository, 20**

| 2757D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 3 | .. | *25.07 | 26.28 | Indocid [AS] |

**indomethacin 100 mg suppository, 20**

| 5128X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 2 | .. | .. | *25.07 | 26.28 | Indocid [AS] |

## ▪ INDOMETHACIN

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**indomethacin 25 mg capsule, 50**

| 2454E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 3 | .. | *16.69 | 17.90 | [a] Arthrexin [AF] |
| | | | [B]4.04 | *20.73 | 17.90 | [a] Indocid [AS] |

## ▪ INDOMETHACIN

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**indomethacin 25 mg capsule, 50**

| 5126T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 2 | .. | .. | *16.69 | 17.90 | [a] Arthrexin [AF] |
| | | | [B]4.04 | *20.73 | 17.90 | [a] Indocid [AS] |

*Oxicams*

## ▪ MELOXICAM

**Note** The use of this drug for the treatment of the following conditions is not subsidised through the PBS:
(a) acute pain;
(b) soft tissue injury;
(c) arthrosis without an inflammatory component.

**Note** Pharmaceutical benefits that have the form meloxicam tablet 7.5 mg and pharmaceutical benefits that have the form meloxicam capsule 7.5 mg are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form meloxicam tablet 15 mg and pharmaceutical benefits that have the form meloxicam capsule 15 mg are equivalent for the purposes of substitution.

**Restricted benefit**

Osteoarthritis

**Clinical criteria:**

- Patient must be symptomatic.

**Restricted benefit**

Rheumatoid arthritis

**Clinical criteria:**

- Patient must be symptomatic.

**meloxicam 15 mg tablet, 30**

| 8562P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | .. | 15.18 | 16.39 | [a] APO-Meloxicam [TX] | [a] Chem mart Meloxicam 15 mg [CH] |
| | | | | | | [a] Meloxiauro 15 [DO] | [a] Meloxibell [GQ] |
| | | | | | | [a] Meloxicam AN [EA] | [a] Meloxicam-GA [ED] |
| | | | | | | [a] Meloxicam Ranbaxy [RA] | [a] Meloxicam Sandoz [SZ] |
| | | | | | | [a] Movalis 15 [RW] | [a] Moxicam 15 [AF] |
| | | | | | | [a] Pharmacor Meloxicam 15 [CR] | [a] Terry White Chemists Meloxicam 15 mg [TW] |
| | | | [B]2.50 | 17.68 | 16.39 | [a] Mobic [BY] | |

**meloxicam 7.5 mg capsule, 30**

| 8887R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | .. | 13.89 | 15.10 | [a] APO-Meloxicam [TX] | [a] Chem mart Meloxicam [CH] |
| | | | | | | [a] Meloxicam Sandoz [SZ] | [a] Movalis 7.5 [RW] |
| | | | | | | [a] Moxicam [AF] | [a] Terry White Chemists Meloxicam [TW] |
| | | | [B]2.50 | 16.39 | 15.10 | [a] Mobic [BY] | |

**meloxicam 7.5 mg tablet, 30**

| 8561N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | .. | 13.89 | 15.10 | [a] APO-Meloxicam [TX] | [a] Chem mart Meloxicam 7.5 mg [CH] |
| | | | | | | [a] Meloxiauro 7.5 [DO] | [a] Meloxibell [GQ] |
| | | | | | | [a] Meloxicam AN [EA] | [a] Meloxicam-GA [ED] |
| | | | | | | [a] Meloxicam Ranbaxy [RA] | [a] Meloxicam Sandoz [SZ] |
| | | | | | | [a] Movalis 7.5 [RW] | [a] Moxicam 7.5 [AF] |
| | | | | | | [a] Pharmacor Meloxicam 7.5 [CR] | [a] Terry White Chemists Meloxicam 7.5 mg [TW] |
| | | | [B]2.50 | 16.39 | 15.10 | [a] Mobic [BY] | |

**meloxicam 15 mg capsule, 30**

| 8888T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | .. | 15.18 | 16.39 | [a] APO-Meloxicam [TX] | [a] Chem mart Meloxicam [CH] |
| | | | | | | [a] Meloxicam Sandoz [SZ] | [a] Movalis 15 [RW] |
| | | | | | | [a] Moxicam [AF] | [a] Terry White Chemists Meloxicam [TW] |
| | | | [B]2.50 | 17.68 | 16.39 | [a] Mobic [BY] | |

## ▪ PIROXICAM

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**piroxicam 20 mg dispersible tablet, 25**

| 1896T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 3 | .. | 15.87 | 17.08 | [a] Mobilis D-20 [AF] |
| | | | [B]8.00 | 23.87 | 17.08 | [a] Feldene-D [PF] |

**piroxicam 20 mg dispersible tablet, 25**

| 5202T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 15.87 | 17.08 | [a] Mobilis D-20 [AF] |
| | | | [B]8.00 | 23.87 | 17.08 | [a] Feldene-D [PF] |

**piroxicam 20 mg capsule, 25**

| 1898X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | .. | 15.87 | 17.08 | [a] GenRx Piroxicam [GX] | [a] Mobilis 20 [AF] |
| | | | [B]8.00 | 23.87 | 17.08 | [a] Feldene [PF] | |

**piroxicam 20 mg capsule, 25**

| 5204X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 15.87 | 17.08 | [a] GenRx Piroxicam [GX] | [a] Mobilis 20 [AF] |
| | | | [B]8.00 | 23.87 | 17.08 | [a] Feldene [PF] | |

**piroxicam 10 mg dispersible tablet, 50**

| 1895R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 3 | .. | 16.12 | 17.33 | Mobilis D-10 [AF] |

**piroxicam 10 mg dispersible tablet, 50**

| 5201R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 16.12 | 17.33 | Mobilis D-10 [AF] |

**piroxicam 10 mg capsule, 50**

| 1897W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | .. | 16.12 | 17.33 | [a] GenRx Piroxicam [GX] | [a] Mobilis 10 [AF] |
| | | | [B]8.00 | 24.12 | 17.33 | [a] Feldene [PF] | |

**piroxicam 10 mg capsule, 50**

| 5203W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 16.12 | 17.33 | [a] GenRx Piroxicam [GX] | [a] Mobilis 10 [AF] |
| | | | [B]8.00 | 24.12 | 17.33 | [a] Feldene [PF] | |

*Propionic acid derivatives*

## ▪ IBUPROFEN

**ibuprofen 400 mg tablet, 30**

| 3192B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | .. | .. | 13.01 | 14.22 | [a] APO-Ibuprofen 400 [TX] | [a] Brufen [GO] |

**ibuprofen 400 mg tablet, 30**

| 5124Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 13.01 | 14.22 | [a] APO-Ibuprofen 400 [TX] | [a] Brufen [GO] |

## ▪ IBUPROFEN

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**ibuprofen 400 mg tablet, 30**

| 3190X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 3 | 3 | .. | *16.84 | 18.05 | [a] APO-Ibuprofen 400 [TX] | [a] Brufen [GO] |

## ▪ IBUPROFEN

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**ibuprofen 400 mg tablet, 30**

| 5123P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 3 | .. | .. | *16.84 | 18.05 | [a] APO-Ibuprofen 400 [TX] | [a] Brufen [GO] |

## ▪ KETOPROFEN

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**ketoprofen 200 mg modified release capsule, 28**

| 1590Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 3 | .. | 22.12 | 23.33 | [a] Oruvail SR [AV] |
| | | | [B]1.92 | 24.04 | 23.33 | [a] Orudis SR 200 [SW] |

**ketoprofen 200 mg modified release capsule, 28**

| 5136H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 22.12 | 23.33 | [a] Oruvail SR [AV] |
| | | | [B]1.92 | 24.04 | 23.33 | [a] Orudis SR 200 [SW] |

## ▪ NAPROXEN

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**naproxen 1 g modified release tablet, 28**

| 1615B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 3 | .. | 17.65 | 18.86 | [a] Proxen SR 1000 [IY] |
| | | | [B]1.12 | 18.77 | 18.86 | [a] Naprosyn SR1000 [IX] |

**naproxen 250 mg tablet, 50**

| 1674D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 3 | .. | *18.35 | 19.56 | [a] Inza 250 [AF] |
| | | | [B]2.24 | *20.59 | 19.56 | [a] Naprosyn [IX] |

**naproxen 750 mg modified release tablet, 28**

| 1614Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 3 | .. | 16.01 | 17.22 | [a] Proxen SR 750 [IY] |
| | | | [B]1.06 | 17.07 | 17.22 | [a] Naprosyn SR750 [IX] |

**naproxen 500 mg tablet, 50**

| 1659H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 3 | .. | 16.46 | 17.67 | [a] Inza 500 [AF] |
| | | | [B]1.12 | 17.58 | 17.67 | [a] Naprosyn [IX] |

## ▪ NAPROXEN

**Authority required (STREAMLINED)**

***4159***

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component, **AND**
- Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

**Authority required (STREAMLINED)**

***4124***

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease, **AND**

- Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

**naproxen 125 mg/5 mL oral liquid, 474 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1658G NP | ‡1 | 3 | .. | 121.27 | 38.80 | Phebra Naproxen Suspension [PL] |

## ▪ NAPROXEN

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**naproxen 1 g modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5179N DP | 1 | .. | .. | 17.65 | 18.86 | [a] Proxen SR 1000 [IY] |
| | | | [B]1.12 | 18.77 | 18.86 | [a] Naprosyn SR1000 [IX] |

**naproxen 250 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5176K DP | 2 | .. | .. | *18.35 | 19.56 | [a] Inza 250 [AF] |
| | | | [B]2.24 | *20.59 | 19.56 | [a] Naprosyn [IX] |

**naproxen 750 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5178M DP | 1 | .. | .. | 16.01 | 17.22 | [a] Proxen SR 750 [IY] |
| | | | [B]1.06 | 17.07 | 17.22 | [a] Naprosyn SR750 [IX] |

**naproxen 500 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5177L DP | 1 | .. | .. | 16.46 | 17.67 | [a] Inza 500 [AF] |
| | | | [B]1.12 | 17.58 | 17.67 | [a] Naprosyn [IX] |

## ▪ NAPROXEN

**Note** Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**naproxen sodium 550 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1795L NP | 1 | 3 | .. | 16.61 | 17.82 | [a] Crysanal [IY] |
| | | | [B]1.89 | 18.50 | 17.82 | [a] Anaprox 550 [IX] |

## ▪ NAPROXEN

**Note** Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**naproxen sodium 550 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5186Y DP | 1 | .. | .. | 16.61 | 17.82 | [a] Crysanal [IY] |
| | | | [B]1.89 | 18.50 | 17.82 | [a] Anaprox 550 [IX] |

*Fenamates*

## ▪ MEFENAMIC ACID

**Restricted benefit**
Dysmenorrhoea
**Restricted benefit**
Menorrhagia

**mefenamic acid 250 mg capsule, 50**

| 1824B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 20.80 | 22.01 | Ponstan [PF] |

*Coxibs*

## ▪ CELECOXIB

**Note** The use of this drug for the treatment of the following conditions is not subsidised through the PBS:
(a) acute pain;
(b) soft tissue injury;
(c) arthrosis without an inflammatory component.

**Restricted benefit**
Osteoarthritis
**Clinical criteria:**
- The treatment must be for symptomatic treatment.

**Restricted benefit**
Rheumatoid arthritis
**Clinical criteria:**
- The treatment must be for symptomatic treatment.

**celecoxib 200 mg capsule, 30**

| 8440F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | .. | 18.03 | 19.24 | [a] APO-Celecoxib [TX] | [a] Blooms the Chemist Celecoxib [IB] |
| | | | | | | [a] Celaxib [AF] | [a] Celebrex [PF] |
| | | | | | | [a] Celecoxib AN [EA] | [a] Celecoxib GH [GQ] |
| | | | | | | [a] Celecoxib RBX [RA] | [a] Celecoxib Sandoz [SZ] |
| | | | | | | [a] Celexi [RW] | [a] Chem mart Celecoxib [CH] |
| | | | | | | [a] Terry White Chemists Celecoxib [TW] | |

**celecoxib 100 mg capsule, 60**

| 8439E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | .. | 18.03 | 19.24 | [a] APO-Celecoxib [TX] | [a] Blooms the Chemist Celecoxib [IB] |
| | | | | | | [a] Celaxib [AF] | [a] Celebrex [PF] |
| | | | | | | [a] Celecoxib AN [EA] | [a] Celecoxib GH [GQ] |
| | | | | | | [a] Celecoxib RBX [RA] | [a] Celecoxib Sandoz [SZ] |
| | | | | | | [a] Celexi [RW] | [a] Chem mart Celecoxib [CH] |
| | | | | | | [a] Terry White Chemists Celecoxib [TW] | |

# SPECIFIC ANTIRHEUMATIC AGENTS

*Quinolines*

## ▪ HYDROXYCHLOROQUINE

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

**hydroxychloroquine sulfate 200 mg tablet, 100**

| 1512N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 25.15 | 26.36 | [a] APO- Hydroxychloroquine [TX] | [a] Chem mart Hydroxychloroquine [CH] |
| | | | | | | [a] Hequinel [RW] | [a] Hydroxychloroquine AN [EA] |
| | | | | | | [a] Hydroxychloroquine GH [GQ] | [a] Hydroxychloroquine RBX [RA] |
| | | | | | | [a] Plaquenil [SW] | [a] Terry White Chemists Hydroxychloroquine [TW] |

*Gold preparations*

## ▪ AURANOFIN

**Caution** Regular blood and urine checks are essential.

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

**auranofin 3 mg tablet, 100**

| 10932J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 3 | .. | 393.48 | 38.80 | Ridaura [GH] |

**auranofin 3 mg capsule, 60**

| 2022K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 773.65 | 38.80 | Ridaura [BZ] |

**auranofin 3 mg tablet, 60**

| 1095P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 238.01 | 38.80 | Ridaura [GH] |

## ▪ SODIUM AUROTHIOMALATE

**Caution** Regular blood and urine checks are essential.

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

**sodium aurothiomalate 10 mg/0.5 mL injection, 10 x 0.5 mL ampoules**

| 2016D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 77.48 | 38.80 | Myocrisin [SW] |

**sodium aurothiomalate 20 mg/0.5 mL injection, 10 x 0.5 mL ampoules**

| 2017E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 113.23 | 38.80 | Myocrisin [SW] |

**sodium aurothiomalate 50 mg/0.5 mL injection, 10 x 0.5 mL ampoules**

| 2018F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 137.22 | 38.80 | Myocrisin [SW] |

*Penicillamine and similar agents*

## ▪ PENICILLAMINE

**Caution** Regular blood and urine checks are essential.

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

**penicillamine 250 mg tablet, 100**

| 2838J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 51.35 | 38.80 | D-Penamine [AL] |

**penicillamine 125 mg tablet, 100**

| 2721F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 45.17 | 38.80 | D-Penamine [AL] |

# ▪ MUSCLE RELAXANTS

## MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

*Other centrally acting agents*

## ▪ BACLOFEN

**baclofen 10 mg tablet, 100**

| 2729P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 21.07 | 22.28 | [a] Chem mart Baclofen [CH]<br>[a] GenRx Baclofen [GX]<br>[a] Stelax 10 [RW] | [a] Clofen 10 [AF]<br>[a] Lioresal 10 [NV]<br>[a] Terry White Chemists Baclofen [TW] |

**baclofen 25 mg tablet, 100**

| 2730Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 32.90 | 34.11 | [a] Chem mart Baclofen [CH]<br>[a] GenRx Baclofen [GX]<br>[a] Stelax 25 [RW] | [a] Clofen 25 [AF]<br>[a] Lioresal 25 [NV]<br>[a] Terry White Chemists Baclofen [TW] |

## MUSCLE RELAXANTS, DIRECTLY ACTING AGENTS

*Dantrolene and derivatives*

### ▪ DANTROLENE

**Restricted benefit**

Chronic spasticity

**dantrolene sodium 50 mg capsule, 100**

| 1780Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 76.20 | 38.80 | Dantrium [PF] |

**dantrolene sodium 25 mg capsule, 100**

| 1779P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 75.67 | 38.80 | Dantrium [PF] |

# ▪ ANTIGOUT PREPARATIONS

## ANTIGOUT PREPARATIONS

*Preparations inhibiting uric acid production*

### ▪ ALLOPURINOL

**Note** The dose should be adjusted in accordance with renal function.

**allopurinol 300 mg tablet, 60**

| 2604C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 14.61 | 15.82 | [a] Allopurinol Sandoz [SZ]<br>[a] APO-Allopurinol [TX]<br>[a] Progout 300 [AF] | [a] Allosig [RF]<br>[a] Chem mart Allopurinol [CH]<br>[a] Terry White Chemists Allopurinol [TW] |
| | | | [B]3.48 | 18.09 | 15.82 | [a] Zyloprim [RW] | |

### ▪ ALLOPURINOL

**Note** The dose should be adjusted in accordance with renal function.

**Note** For item codes 2600W and 1557Y, pharmaceutical benefits that have the form tablet 100 mg are equivalent for the purposes of substitution.

**allopurinol 100 mg tablet, 100**

| 1557Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | .. | *15.95 | 17.16 | [a] Progout 100 [AF] |

**allopurinol 100 mg tablet, 200**

| 2600W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 15.95 | 17.16 | [a] Allopurinol Sandoz [SZ]<br>[a] APO-Allopurinol [TX]<br>[a] Progout 100 [AF] | [a] Allosig [RF]<br>[a] Chem mart Allopurinol [CH]<br>[a] Terry White Chemists Allopurinol [TW] |
| | | | [B]3.47 | 19.42 | 17.16 | [a] Zyloprim [RW] | |

### ▪ FEBUXOSTAT

**Note Shared Care Model**:

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

**Authority required**

Chronic gout

**Clinical criteria:**

- The condition must be either chronic gouty arthritis or chronic tophaceous gout, **AND**
- Patient must have a medical contraindication to allopurinol; OR
- Patient must have a documented history of allopurinol hypersensitivity syndrome; OR
- Patient must have an intolerance to allopurinol necessitating permanent treatment discontinuation.

**febuxostat 80 mg tablet, 28**

| 10445R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 50.94 | 38.80 | Adenuric [FK] |

*Preparations increasing uric acid excretion*

## ▪ PROBENECID

**probenecid 500 mg tablet, 100**

| 1940D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 70.91 | 38.80 | Pro-Cid [PL] |

*Preparations with no effect on uric acid metabolism*

## ▪ COLCHICINE

**colchicine 500 microgram tablet, 30**

| 3410L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.07 | 16.28 | [a] Lengout [LN] |
| | | | [B]2.90 | 17.97 | 16.28 | [a] Colgout [AS] |

# ▪ DRUGS FOR TREATMENT OF BONE DISEASES

## DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

*Bisphosphonates*

## ▪ ALENDRONATE

**Restricted benefit**

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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**Restricted benefit**

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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**Restricted benefit**

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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**alendronate 70 mg tablet, 4**

| 8511Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.00 | 16.21 | [a] Alendrobell 70mg [GQ]<br>[a] Alendronate Sandoz [SZ]<br>[a] APO-Alendronate [TX]<br>[a] Fonat [AL] | [a] Alendronate AN [EA]<br>[a] Alendro Once Weekly [RW]<br>[a] Densate 70 [DO] |

## ▪ CLODRONATE

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Hypercalcaemia of malignancy

**Clinical criteria:**

- Patient must have a malignancy refractory to anti-neoplastic therapy.

**Restricted benefit**

Multiple myeloma

**Restricted benefit**

Bone metastases

**Clinical criteria:**

- The condition must be due to breast cancer.

### clodronate sodium 800 mg tablet, 60

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8265B NP | 1 | 2 | .. | 365.66 | 38.80 | Bonefos 800 mg [BN] |

### clodronate sodium 400 mg capsule, 100

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8132B NP | 1 | 2 | .. | 309.26 | 38.80 | Bonefos [BN] |

## ▪ IBANDRONATE

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Bone metastases

**Clinical criteria:**

- The condition must be due to breast cancer.

### ibandronate 50 mg tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9357L NP | 1 | 2 | .. | 317.38 | 38.80 | Bondronat [RO] |

## ▪ PAMIDRONATE DISODIUM

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Symptomatic Paget disease of bone

### pamidronate disodium 60 mg/10 mL injection, 10 mL vial

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8463K NP | 1 | .. | .. | 70.51 | 38.80 | Pamisol [PF] |

### pamidronate disodium 15 mg/5 mL injection, 5 mL vial

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8461H NP | 4 | .. | .. | *70.51 | 38.80 | Pamisol [PF] |

### pamidronate disodium 30 mg/10 mL injection, 10 mL vial

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8462J NP | 2 | .. | .. | *70.51 | 38.80 | Pamisol [PF] |

## ▪ RISEDRONATE

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Symptomatic Paget disease of bone

**risedronate sodium 30 mg tablet, 28**

| 8482K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 175.09 | 38.80 | Actonel [UA] |

## ▪ RISEDRONATE

**Restricted benefit**

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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**Restricted benefit**

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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**Restricted benefit**

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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**risedronate sodium 5 mg tablet, 28**

| 8481J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 35.10 | 36.31 | Actonel [UA] |

**risedronate sodium 35 mg tablet, 4**

| 8621R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 35.10 | 36.31 | [a] Acris Once-a-Week [AF]<br>[a] Risedronate AN [EA]<br>[a] Risedro once a week [RW] | [a] APO-Risedronate [TX]<br>[a] Risedronate Sandoz [SZ] |

**risedronate sodium 150 mg tablet, 1**

| 9391G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 37.12 | 38.33 | [a] Acris Once-a-Month [AF]<br>[a] APO-Risedronate [TX] | [a] Actonel Once-a-Month [UA]<br>[a] ATELVIA ONCE-A-MONTH [GN] |

**RISEDRONATE SODIUM Tablet 35 mg (enteric coated), 4**

| 8972F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 35.10 | 36.31 | Actonel EC [UA] |

## ▪ ZOLEDRONIC ACID

**Note** Pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL vial and pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL bag are equivalent for the purposes of substitution.

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**Authority required (STREAMLINED)**

***5710***

Symptomatic Paget disease of bone

Only 1 treatment each year per patient will be PBS-subsidised

**zoledronic acid 5 mg/100 mL injection, 100 mL vial**

9350D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 370.31 | 38.80 | [a] Aclasta [HX]<br>[a] Zoledasta [TX] | [a] Osteovan [SZ] |

**zoledronic acid 5 mg/100 mL injection, 100 mL bag**

10571J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 370.31 | 38.80 | [a] Ostira [PF] |

## ▪ ZOLEDRONIC ACID

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Note** Pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL vial and pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL bag are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

***6308***

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***6313***

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -3.0 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***6318***

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**zoledronic acid 5 mg/100 mL injection, 100 mL vial**

9288W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 370.31 | 38.80 | [a] Aclasta [HX]<br>[a] Zoledasta [TX] | [a] Osteovan [SZ] |

**zoledronic acid 5 mg/100 mL injection, 100 mL bag**

10555M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 370.31 | 38.80 | [a] Ostira [PF] |

*Bisphosphonates, combinations*

## ▪ ALENDRONATE + COLECALCIFEROL

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority required (STREAMLINED)**

***6306***

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***6325***

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***6319***

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

### alendronate 70 mg + colecalciferol 140 microgram tablet, 4

9183H (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 15.00 | 16.21 | [a] Alendronate plus D3-DRLA [RZ]<br>[a] APO-Alendronate Plus D3 70 mg/140 mcg [TX]<br>[a] FonatPlus [AF] | [a] Alendronate Plus D3 Sandoz [SZ]<br>[a] Chem mart Alendronate Plus D3 70 mg/140 mcg [CH]<br>[a] Terry White Chemists Alendronate Plus D3 70 mg/140 mcg [TW] |
| | | [B]2.94 | 17.94 | 16.21 | [a] Dronalen Plus [AL] | |
| | | [B]5.20 | 20.20 | 16.21 | [a] Fosamax Plus 70 mg/140 mcg [MK] | |

## ▪ ALENDRONATE + COLECALCIFEROL

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Note** Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.

**Authority required (STREAMLINED)**

***6307***

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***6320***

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***6315***

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**alendronate 70 mg + colecalciferol 70 microgram tablet, 4**

| 9012H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.00 | 16.21 | [a] Alendronate plus D3-DRLA [RZ]<br>[a] APO-Alendronate Plus D3 70 mg/70 mcg [TX]<br>[a] FonatPlus [AF] | [a] Alendronate Plus D3 Sandoz [SZ]<br>[a] Chem mart Alendronate Plus D3 70 mg/70 mcg [CH]<br>[a] Terry White Chemists Alendronate Plus D3 70 mg/70 mcg [TW] |
| | | | [B]5.20 | 20.20 | 16.21 | [a] Fosamax Plus [MK] | |

## ▪ ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority required (STREAMLINED)**

***6306***

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***6325***

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***6319***

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack**

| 9351E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 15.00 | 16.21 | [a] Dronalen Plus D-Cal [AF] | [a] ReddyMax Plus D-Cal [RZ] |
| | | | [B]9.71 | 24.71 | 16.21 | [a] Fosamax Plus D-Cal [MK] | |

## ▪ RISEDRONATE (&) CALCIUM CARBONATE

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority required (STREAMLINED)**

***6306***

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***6325***

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***6319***

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**risedronate sodium 35 mg tablet [4] (&) calcium (as carbonate) 500 mg tablet [24], 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8899J NP | ‡1 | 5 | .. | 35.10 | 36.31 | Acris Combi [AF] |

**RISEDRONATE SODIUM and CALCIUM CARBONATE Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8973G NP | ‡1 | 5 | .. | 35.10 | 36.31 | Actonel EC Combi [UA] |

## ▪ RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority required (STREAMLINED)**

***6306***

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***6325***

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***6319***

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8974H NP | ‡1 | 5 | .. | 35.10 | 36.31 | Actonel EC Combi D [UA] |

*Other drugs affecting bone structure and mineralization*

## ▪ CALCITRIOL

**Authority required (STREAMLINED)**

***5401***

Hypocalcaemia

**Clinical criteria:**

- The condition must be due to renal disease.

**Authority required (STREAMLINED)**

***5255***

Hypoparathyroidism

**Authority required (STREAMLINED)**

***5089***

Hypophosphataemic rickets

**Authority required (STREAMLINED)**

***5114***

Vitamin D-resistant rickets

**Authority required (STREAMLINED)**

***5402***

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**calcitriol 0.25 microgram capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2502Q NP | 1 | 3 | .. | 27.21 | 28.42 | [a] APO-Calcitriol [TX]<br>[a] Calcitriol AN [EA]<br>[a] Sical [AF] | [a] Calciprox [ER]<br>[a] Kosteo [RW] |
| | | | [B]2.29 | 29.50 | 28.42 | [a] Rocaltrol [RO] | |

## ▪ DENOSUMAB

**Note** Denosumab is not PBS-subsidised for use in patients who have undergone curative surgical resection.

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***4504***

Giant cell tumour of bone

**Clinical criteria:**

- Patient must be one in whom surgical resection is not feasible; OR
- Patient must be one in whom surgical resection is possible but surgery would result in significant morbidity.

**Population criteria:**

- Patient must be an adult; OR
- Patient must be a skeletally mature adolescent.

**denosumab 120 mg/1.7 mL injection, 1.7 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10061M NP | 1 | 5 | .. | 501.67 | 38.80 | Xgeva [AN] |

## ▪ DENOSUMAB

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

**Authority required (STREAMLINED)**
***4158***
Bone metastases
**Clinical criteria:**
- The condition must be due to breast cancer.

**Authority required (STREAMLINED)**
***4150***
Bone metastases
**Clinical criteria:**
- The condition must be due to castration-resistant prostate cancer.

### denosumab 120 mg/1.7 mL injection, 1.7 mL vial

5110Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 501.67 | 38.80 | Xgeva [AN] |

NP

## ▪ DENOSUMAB

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority required (STREAMLINED)**
***6548***
Osteoporosis
**Population criteria:**
- Patient must be aged 70 years or older.

**Clinical criteria:**
- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**
***6524***
Established osteoporosis
**Clinical criteria:**
- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

### denosumab 60 mg/mL injection, 1 mL syringe

5457F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 271.49 | 38.80 | Prolia [AN] |

NP

## ▪ RALOXIFENE

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority required (STREAMLINED)**
***6314***
Established post-menopausal osteoporosis
**Clinical criteria:**
- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

### raloxifene hydrochloride 60 mg tablet, 28

8363E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 44.85 | 38.80 | [a] APO-Raloxifene [TX] | [a] Evifyne [EL] |

NP

[a] Evista [LY] [a] Fixta 60 [DO]
[a] Raloxifene AMNEAL [ED] [a] Raloxifene AN [EA]

## ▪ TERIPARATIDE

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

**Authority required**

Severe established osteoporosis

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

**Clinical criteria:**

- Patient must be at very high risk of fracture, **AND**
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less, **AND**
- Patient must have had 2 or more fractures due to minimal trauma, **AND**
- Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, **AND**
- The treatment must be the sole PBS-subsidised agent, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy**.** Details must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.

**Note** Details of accepted toxicities including severity can be found on the Department of Human Services website at www.humanservices.gov.au.

**Authority required**

Severe established osteoporosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

**Note** Up to a maximum of 18 pens will be reimbursed through the PBS.

**teriparatide 20 microgram injection, 2.4 mL cartridge**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9411H | 1 | 5 | .. | 411.80 | 38.80 | Forteo [LY] |

# ▪ NERVOUS SYSTEM

# ▪ ANALGESICS

## OPIOIDS

*Natural opium alkaloids*

## ▪ CODEINE

**codeine phosphate 30 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1214X NP | 1 | .. | .. | 20.50 | 21.71 | Fawns and McAllan Proprietary Limited [FM] |

## ▪ CODEINE

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**codeine phosphate 30 mg tablet, 20**

| 5063L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 20.50 | 21.71 | Fawns and McAllan Proprietary Limited [FM] |

## ▪ HYDROMORPHONE

**Caution** The risk of drug dependence is high.

**hydromorphone hydrochloride 2 mg/mL injection, 5 x 1 mL ampoules**

| 8420E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 28.53 | 29.74 | Dilaudid [MF] |

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

| 8421F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 33.36 | 34.57 | Dilaudid-HP [MF] |

## ▪ HYDROMORPHONE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**hydromorphone hydrochloride 8 mg tablet, 20**

| 5117H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 31.37 | 32.58 | Dilaudid [MF] |

**hydromorphone hydrochloride 4 mg tablet, 20**

| 5116G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 22.96 | 24.17 | Dilaudid [MF] |

**hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL**

| 5132D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 69.31 | 38.80 | Dilaudid [MF] |

**hydromorphone hydrochloride 2 mg tablet, 20**

| 5115F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 20.69 | 21.90 | Dilaudid [MF] |

## ▪ HYDROMORPHONE

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Restricted benefit**

Severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**hydromorphone hydrochloride 8 mg tablet, 20**

| 8543P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 31.37 | 32.58 | Dilaudid [MF] |

**hydromorphone hydrochloride 4 mg tablet, 20**

| 8542N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 22.96 | 24.17 | Dilaudid [MF] |

**hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8424J NP | 1 | .. | .. | 69.31 | 38.80 | Dilaudid [MF] |

**hydromorphone hydrochloride 2 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8541M NP | 1 | .. | .. | 20.69 | 21.90 | Dilaudid [MF] |

## ▪ HYDROMORPHONE

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**hydromorphone hydrochloride 8 mg modified release tablet, 14**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9406C NP | 1 | .. | .. | 36.64 | 37.85 | Jurnista [JC] |

**hydromorphone hydrochloride 64 mg modified release tablet, 14**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9409F NP | 1 | .. | .. | 135.22 | 38.80 | Jurnista [JC] |

**hydromorphone hydrochloride 4 mg modified release tablet, 14**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9299K NP | 1 | .. | .. | 32.12 | 33.33 | Jurnista [JC] |

**hydromorphone hydrochloride 16 mg modified release tablet, 14**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9407D NP | 1 | .. | .. | 51.33 | 38.80 | Jurnista [JC] |

**hydromorphone hydrochloride 32 mg modified release tablet, 14**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9408E NP | 1 | .. | .. | 82.83 | 38.80 | Jurnista [JC] |

## ▪ MORPHINE

**Caution** The risk of drug dependence is high.

**morphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10869C NP | 1 | .. | .. | 30.23 | 31.44 | Morphine Juno [JU] |

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1647Q NP | 1 | .. | .. | 23.92 | 25.13 | Hospira Pty Limited [PF] |

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10874H NP | 1 | .. | .. | 23.78 | 24.99 | Morphine Juno [JU] |

**morphine hydrochloride 100 mg/5 mL injection, 5 x 5 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10878M NP | 1 | .. | .. | 40.98 | 38.80 | Morphine Juno [JU] |

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1645N NP MW | 1 | .. | .. | 21.82 | 23.03 | Hospira Pty Limited [PF] |

**morphine tartrate 120 mg/1.5 mL injection, 5 x 1.5 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1607N NP | 1 | .. | .. | 42.74 | 38.80 | Hospira Pty Limited [PF] |

## ▪ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5170D DP | 1 | .. | .. | 23.92 | 25.13 | Hospira Pty Limited [PF] |

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10858L DP | 1 | .. | .. | 23.78 | 24.99 | Morphine Juno [JU] |

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5169C DP | 1 | .. | .. | 21.82 | 23.03 | Hospira Pty Limited [PF] |

## ▪ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution.

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1644M NP MW | 1 | .. | .. | 20.42 | 21.63 | [a] Hospira Pty Limited [PF] |

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10864T NP MW | 1 | .. | .. | 20.42 | 21.63 | [a] Morphine Juno [JU] |

## ▪ MORPHINE

**Caution** The risk of drug dependence is high.

**Authority required**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must be due to cancer, **AND**
- The condition must be unresponsive to non-opioid analgesics.

**morphine sulfate 200 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8453X NP | 1 | .. | .. | 116.58 | 38.80 | MS Contin [MF] |

**morphine sulfate 200 mg modified release granules, 28 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8454Y NP | 1 | .. | .. | 154.66 | 38.80 | MS Contin Suspension 200 mg [MF] |

## ▪ MORPHINE

**Caution** The risk of drug dependence is high.

**Restricted benefit**

Severe disabling pain

**Clinical criteria:**

- The condition must be due to cancer, **AND**
- The condition must be unresponsive to non-opioid analgesics.

**morphine sulfate 20 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8670H NP | 1 | .. | .. | 19.43 | 20.64 | Sevredol [MF] |

**morphine sulfate 10 mg tablet, 20**

| 8669G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 18.61 | 19.82 | Sevredol [MF] |

## ▪ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Note** Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution.

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

| 5168B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 20.42 | 21.63 | [a] Hospira Pty Limited [PF] |

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

| 10863R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 20.42 | 21.63 | [a] Morphine Juno [JU] |

## ▪ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Restricted benefit**

Severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**morphine hydrochloride 5 mg/mL oral liquid, 200 mL**

| 2123R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 25.93 | 27.14 | Ordine 5 [MF] |

**morphine hydrochloride 2 mg/mL oral liquid, 200 mL**

| 2122Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 23.84 | 25.05 | Ordine 2 [MF] |

**morphine hydrochloride 10 mg/mL oral liquid, 200 mL**

| 2124T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 29.52 | 30.73 | Ordine 10 [MF] |

**morphine sulfate 30 mg tablet, 20**

| 1646P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 18.36 | 19.57 | Anamorph [RW] |

## ▪ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**morphine Sachet containing controlled release granules for oral suspension, 30 mg per sachet, 28**

| 8146R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 62.23 | 38.80 | MS Contin Suspension 30 mg [MF] |

**morphine sulfate 60 mg modified release capsule, 14**

| 8492Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 37.35 | 38.56 | MS Mono [MF] |

**morphine sulfate 10 mg modified release tablet, 28**

| 1653B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 23.59 | 24.80 | [a] Momex SR 10 [RW]<br>[a] MORPHINE MR APOTEX [TX]<br>[a] MS Contin [MF] | [a] Morphine MR AN [EA]<br>[a] Morphine MR Mylan [AF] |

**morphine sulfate 30 mg modified release tablet, 28**

| 1654C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 37.37 | 38.58 | [a] Momex SR 30 [RW]<br>[a] MORPHINE MR APOTEX [TX]<br>[a] MS Contin [MF] | [a] Morphine MR AN [EA]<br>[a] Morphine MR Mylan [AF] |

**morphine sulfate 30 mg modified release capsule, 14**

| 8491X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 27.22 | 28.43 | MS Mono [MF] |

**morphine Capsule 100 mg (containing sustained release pellets), 28**

| 2841M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 69.86 | 38.80 | Kapanol [YN] |

**morphine sulfate 5 mg modified release tablet, 28**

| 8035X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 21.47 | 22.68 | MS Contin [MF] |

**morphine sulfate 90 mg modified release capsule, 14**

| 8493B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 42.18 | 38.80 | MS Mono [MF] |

**morphine Capsule 50 mg (containing sustained release pellets), 28**

| 2840L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 43.82 | 38.80 | Kapanol [YN] |

**morphine sulfate 120 mg modified release capsule, 14**

| 8494C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 54.94 | 38.80 | MS Mono [MF] |

**morphine Sachet containing controlled release granules for oral suspension, 60 mg per sachet, 28**

| 8305D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 69.32 | 38.80 | MS Contin Suspension 60 mg [MF] |

**morphine sulfate 15 mg modified release tablet, 28**

| 8489T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 27.23 | 28.44 | MS Contin [MF] |

**morphine Capsule 20 mg (containing sustained release pellets), 28**

| 2839K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 27.91 | 29.12 | Kapanol [YN] |

**morphine sulfate 100 mg modified release granules, 28 sachets**

| 8306E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 84.32 | 38.80 | MS Contin Suspension 100 mg [MF] |

**morphine sulfate 20 mg modified release granules, 28 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8490W NP | 1 | .. | .. | 60.61 | 38.80 | MS Contin Suspension 20 mg [MF] |

**morphine Capsule 10 mg (containing sustained release pellets), 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8349K NP | 1 | .. | .. | 23.58 | 24.79 | Kapanol [YN] |

**morphine sulfate 100 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1656E NP | 1 | .. | .. | 71.72 | 38.80 | [a] Momex SR 100 [RW]<br>[a] MORPHINE MR APOTEX [TX]<br>[a] MS Contin [MF] | [a] Morphine MR AN [EA]<br>[a] Morphine MR Mylan [AF] |

**morphine sulfate 60 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1655D NP | 1 | .. | .. | 54.95 | 38.80 | [a] Momex SR 60 [RW]<br>[a] MORPHINE MR APOTEX [TX]<br>[a] MS Contin [MF] | [a] Morphine MR AN [EA]<br>[a] Morphine MR Mylan [AF] |

## ▪ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**morphine hydrochloride 5 mg/mL oral liquid, 200 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5238Q DP | 1 | .. | .. | 25.93 | 27.14 | Ordine 5 [MF] |

**morphine hydrochloride 2 mg/mL oral liquid, 200 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5237P DP | 1 | .. | .. | 23.84 | 25.05 | Ordine 2 [MF] |

**morphine hydrochloride 10 mg/mL oral liquid, 200 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5239R DP | 1 | .. | .. | 29.52 | 30.73 | Ordine 10 [MF] |

**morphine sulfate 30 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5163R DP | 1 | .. | .. | 18.36 | 19.57 | Anamorph [RW] |

## ▪ OXYCODONE

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Restricted benefit**

Severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**oxycodone hydrochloride 1 mg/mL oral liquid, 250 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8644Y NP | 1 | .. | .. | 27.34 | 28.55 | OxyNorm Liquid 1mg/mL [MF] |

**oxycodone 30 mg suppository, 12**

| 2481N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 46.45 | 38.80 | Proladone [PL] |

**oxycodone hydrochloride 5 mg capsule, 20**

| 8464L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 16.42 | 17.63 | OxyNorm [MF] |

**oxycodone hydrochloride 10 mg capsule, 20**

| 8501K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 18.70 | 19.91 | OxyNorm [MF] |

**oxycodone hydrochloride 5 mg tablet, 20**

| 2622B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 16.42 | 17.63 | [a] Endone [QA] | [a] Mayne Pharma Oxycodone IR [YN] |
| | | | | | | [a] Oxycodone Aspen [FM] | |

**oxycodone hydrochloride 20 mg capsule, 20**

| 8502L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 22.14 | 23.35 | OxyNorm [MF] |

## ▪ OXYCODONE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**oxycodone hydrochloride 1 mg/mL oral liquid, 250 mL**

| 5190E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 27.34 | 28.55 | OxyNorm Liquid 1mg/mL [MF] |

**oxycodone 30 mg suppository, 12**

| 5194J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 46.45 | 38.80 | Proladone [PL] |

**oxycodone hydrochloride 5 mg capsule, 20**

| 5191F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 16.42 | 17.63 | OxyNorm [MF] |

**oxycodone hydrochloride 10 mg capsule, 20**

| 5197M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 18.70 | 19.91 | OxyNorm [MF] |

**oxycodone hydrochloride 5 mg tablet, 20**

| 5195K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 16.42 | 17.63 | [a] Endone [QA] | [a] Mayne Pharma Oxycodone IR [YN] |
| | | | | | | [a] Oxycodone Aspen [FM] | |

## ▪ OXYCODONE

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note** OxyContin and Novacodone modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**oxycodone hydrochloride 20 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8386J NP | 1 | .. | .. | 37.36 | 38.57 | [a] Novacodone [HX]<br>[a] OxyContin [MF] | [a] Oxycodone Sandoz [SZ] |

**oxycodone hydrochloride 10 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8385H NP | 1 | .. | .. | 27.23 | 28.44 | [a] Novacodone [HX]<br>[a] OxyContin [MF] | [a] Oxycodone Sandoz [SZ] |

**oxycodone hydrochloride 40 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8387K NP | 1 | .. | .. | 54.94 | 38.80 | [a] Novacodone [HX]<br>[a] OxyContin [MF] | [a] Oxycodone Sandoz [SZ] |

**oxycodone hydrochloride 80 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8388L NP | 1 | .. | .. | 80.99 | 38.80 | [a] Novacodone [HX]<br>[a] OxyContin [MF] | [a] Oxycodone Sandoz [SZ] |

## ▪ OXYCODONE

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note** OxyContin modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**oxycodone hydrochloride 15 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9399Q NP | 1 | .. | .. | 33.34 | 34.55 | OxyContin [MF] |

**oxycodone hydrochloride 30 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9400R NP | 1 | .. | .. | 46.92 | 38.80 | OxyContin [MF] |

## ▪ OXYCODONE + NALOXONE

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**oxycodone hydrochloride 10 mg + naloxone hydrochloride 5 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8934F NP | 1 | .. | .. | 32.83 | 34.04 | Targin 10/5mg [MF] |

**oxycodone hydrochloride 80 mg + naloxone hydrochloride 40 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11111T NP | 1 | .. | .. | 94.36 | 38.80 | Targin 80/40 [MF] |

**oxycodone hydrochloride 30 mg + naloxone hydrochloride 15 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10758F NP | 1 | .. | .. | 53.47 | 38.80 | Targin 30/15 mg [MF] |

**oxycodone hydrochloride 5 mg + naloxone hydrochloride 2.5 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8000C NP | 1 | .. | .. | 31.70 | 32.91 | Targin 5/2.5mg [MF] |

**oxycodone hydrochloride 2.5 mg + naloxone hydrochloride 1.25 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10776E NP | 1 | .. | .. | 23.96 | 25.17 | Targin 2.5/1.25 mg [MF] |

**oxycodone hydrochloride 60 mg + naloxone hydrochloride 30 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11102H NP | 1 | .. | .. | 79.72 | 38.80 | Targin 60/30 [MF] |

**oxycodone hydrochloride 15 mg + naloxone hydrochloride 7.5 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10757E NP | 1 | .. | .. | 37.18 | 38.39 | Targin 15/7.5mg [MF] |

**oxycodone hydrochloride 20 mg + naloxone hydrochloride 10 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8935G NP | 1 | .. | .. | 47.32 | 38.80 | Targin 20/10mg [MF] |

**oxycodone hydrochloride 40 mg + naloxone hydrochloride 20 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8936H NP | 1 | .. | .. | 72.42 | 38.80 | Targin 40/20mg [MF] |

*Phenylpiperidine derivatives*

## ▪ FENTANYL

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Note** Pharmaceutical benefits that have the form fentanyl 12 microgram/hour patch are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form fentanyl 25 microgram/hour patch are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form fentanyl 50 microgram/hour patch are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form fentanyl 75 microgram/hour patch are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form fentanyl 100 microgram/hour patch are equivalent for the purposes of substitution.

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**fentanyl 75 microgram/hour patch, 5**

| 5279W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 41.21 | 38.80 | [a] Denpax [AF] |

**fentanyl 75 microgram/hour patch, 5**

| 5440H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 41.21 | 38.80 | [a] Dutran 75 [EA] | [a] Fenpatch 75 [ZP] |

**fentanyl 75 microgram/hour patch, 5**

| 8893C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 41.21 | 38.80 | [a] APO-Fentanyl [TX]<br>[a] Fentanyl Sandoz [SZ] | [a] Durogesic 75 [JC] |

**fentanyl 100 microgram/hour patch, 5**

| 5280X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 47.73 | 38.80 | [a] Denpax [AF] |

**fentanyl 100 microgram/hour patch, 5**

| 5441J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 47.73 | 38.80 | [a] Dutran 100 [EA] | [a] Fenpatch 100 [ZP] |

**fentanyl 100 microgram/hour patch, 5**

| 8894D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 47.73 | 38.80 | [a] APO-Fentanyl [TX]<br>[a] Fentanyl Sandoz [SZ] | [a] Durogesic 100 [JC] |

**fentanyl 50 microgram/hour patch, 5**

| 5278T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 33.88 | 35.09 | [a] Denpax [AF] |

**fentanyl 50 microgram/hour patch, 5**

| 5439G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 33.88 | 35.09 | [a] Dutran 50 [EA] | [a] Fenpatch 50 [ZP] |

**fentanyl 50 microgram/hour patch, 5**

| 8892B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 33.88 | 35.09 | [a] APO-Fentanyl [TX]<br>[a] Fentanyl Sandoz [SZ] | [a] Durogesic 50 [JC] |

**fentanyl 25 microgram/hour patch, 5**

| 5277R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 24.86 | 26.07 | [a] Denpax [AF] |

**fentanyl 25 microgram/hour patch, 5**

| 5438F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 24.86 | 26.07 | [a] Dutran 25 [EA] | [a] Fenpatch 25 [ZP] |

**fentanyl 25 microgram/hour patch, 5**

| 8891Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 24.86 | 26.07 | [a] APO-Fentanyl [TX]<br>[a] Fentanyl Sandoz [SZ] | [a] Durogesic 25 [JC] |

**fentanyl 12 microgram/hour patch, 5**

| 5265D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 22.56 | 23.77 | [a] Denpax [AF] |

**fentanyl 12 microgram/hour patch, 5**

| 5437E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 22.56 | 23.77 | [a] Dutran 12 [EA] | [a] Fenpatch 12 [ZP] |

**fentanyl 12 microgram/hour patch, 5**

| 8878G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 22.56 | 23.77 | [a] APO-Fentanyl [TX]<br>[a] Fentanyl Sandoz [SZ] | [a] Durogesic 12 [JC] |

*Diphenylpropylamine derivatives*

## ▪ METHADONE

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

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

**Restricted benefit**
Severe disabling pain
**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

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

| 1606M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 49.78 | 38.80 | Physeptone [QA] |

**methadone hydrochloride 10 mg tablet, 20**

| 1609Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 19.40 | 20.61 | Physeptone [QA] |

*Oripavine derivatives*

## ▪ BUPRENORPHINE

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

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

**Restricted benefit**
Chronic severe disabling pain
**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**buprenorphine 15 microgram/hour patch, 2**

| 10770W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 47.33 | 38.80 | Norspan [MF] |

**buprenorphine 25 microgram/hour patch, 2**

| 10756D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 61.15 | 38.80 | Norspan [MF] |

**buprenorphine 10 microgram/hour patch, 2**

| 8866P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 40.24 | 38.80 | Norspan [MF] |

**buprenorphine 40 microgram/hour patch, 2**

| 10746N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 81.31 | 38.80 | Norspan [MF] |

**buprenorphine 5 microgram/hour patch, 2**

| 8865N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 28.62 | 29.83 | Norspan [MF] |

**buprenorphine 30 microgram/hour patch, 2**

| 10755C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 67.87 | 38.80 | Norspan [MF] |

**buprenorphine 20 microgram/hour patch, 2**

| 8867Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 54.43 | 38.80 | Norspan [MF] |

*Opioids in combination with non-opioid analgesics*

## ▪ PARACETAMOL + CODEINE

**CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20**

| 3316M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 12.44 | 13.65 | [a] APO- Paracetamol/Codeine 500/30 [TX] | [a] Codalgin Forte [FM] |
| | | | | | | [a] Codapane Forte [AL] | [a] Comfarol Forte [SZ] |
| | | | | | | [a] Paracetamol/Codeine GH 500/30 [GQ] | [a] Prodeine Forte [AV] |
| | | | [B]2.10 | 14.54 | 13.65 | [a] Panadeine Forte [SW] | |

## ▪ PARACETAMOL + CODEINE

**Note** Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of codeine phosphate with paracetamol.

**CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20**

| 1215Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 12.44 | 13.65 | [a] APO- Paracetamol/Codeine 500/30 [TX] | [a] Codalgin Forte [FM] |
| | | | | | | [a] Codapane Forte [AL] | [a] Comfarol Forte [SZ] |
| | | | | | | [a] Paracetamol/Codeine GH 500/30 [GQ] | [a] Prodeine Forte [AV] |
| | | | [B]2.10 | 14.54 | 13.65 | [a] Panadeine Forte [SW] | |

## ▪ PARACETAMOL + CODEINE

**Note** Each authority approval will be limited to no more than 240 tablets per month for no more than 6 months.

**Authority required**

Severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20**

| 8785J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 3 | .. | .. | *15.13 | 16.34 | [a] APO- Paracetamol/Codeine 500/30 [TX] | [a] Codalgin Forte [FM] |
| | | | | | | [a] Codapane Forte [AL] | [a] Comfarol Forte [SZ] |
| | | | | | | [a] Paracetamol/Codeine GH 500/30 [GQ] | [a] Prodeine Forte [AV] |
| | | | [B]6.30 | *21.43 | 16.34 | [a] Panadeine Forte [SW] | |

*Other opioids*

## ▪ TAPENTADOL

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**tapentadol 200 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10091D NP | 1 | .. | .. | 47.62 | 38.80 | Palexia SR [CS] |

**tapentadol 150 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10100N NP | 1 | .. | .. | 40.95 | 38.80 | Palexia SR [CS] |

**tapentadol 50 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10096J NP | 1 | .. | .. | 25.52 | 26.73 | Palexia SR [CS] |

**tapentadol 250 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10092E NP | 1 | .. | .. | 53.28 | 38.80 | Palexia SR [CS] |

**tapentadol 100 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10094G NP | 1 | .. | .. | 33.39 | 34.60 | Palexia SR [CS] |

## ▪ TRAMADOL

**Restricted benefit**

Pain

**Clinical criteria:**

- The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

**tramadol hydrochloride 100 mg/mL oral liquid, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5150C DP | ‡1 | .. | .. | 17.43 | 18.64 | Tramal [CS] |

## ▪ TRAMADOL

**Restricted benefit**

Acute pain

**Clinical criteria:**

- The treatment must be for the short-term.

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5231H DP | 1 | .. | .. | 13.94 | 15.15 | [a] Tramadol ACT [EA]<br>[a] Tramal 100 [CS] | [a] Tramadol Sandoz [SZ] |

## ▪ TRAMADOL

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for severe disabling pain not responding to non-opioid analgesics.

**Restricted benefit**

Pain

**Clinical criteria:**

- The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

**tramadol hydrochloride 150 mg modified release tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8524P NP | 1 | .. | .. | 14.32 | 15.53 | [a] APO-Tramadol SR [TX]<br>[a] Lodam SR 150 [ZP]<br>[a] Tramadol AN SR [EA] | [a] Chem mart Tramadol SR [CH]<br>[a] Terry White Chemists Tramadol SR [TW]<br>[a] Tramadol Sandoz SR [SZ] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Tramadol SR generichealth [GQ]<br>[a] Zydol SR 150 [RW] | [a] Tramedo SR 150 [AF] |
| | | | [B]5.37 | 19.69 | 15.53 | [a] Tramal SR 150 [CS] | |

**tramadol hydrochloride 100 mg/mL oral liquid, 10 mL**

| 8843K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | .. | .. | 17.43 | 18.64 | Tramal [CS] |

**tramadol hydrochloride 50 mg modified release tablet, 20**

| 2527B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 14.24 | 15.45 | Tramal SR 50 [CS] |

**tramadol hydrochloride 100 mg modified release tablet, 20**

| 8523N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 13.50 | 14.71 | [a] APO-Tramadol SR [TX]<br>[a] GA Tramadol SR 100mg [ED]<br>[a] Terry White Chemists Tramadol SR [TW]<br>[a] Tramadol Sandoz SR [SZ]<br>[a] Tramedo SR 100 [AF] | [a] Chem mart Tramadol SR [CH]<br>[a] Lodam SR 100 [ZP]<br>[a] Tramadol AN SR [EA]<br>[a] Tramadol SR generichealth [GQ]<br>[a] Zydol SR 100 [RW] |
| | | | [B]4.49 | 17.99 | 14.71 | [a] Tramal SR 100 [CS] | |

**tramadol hydrochloride 200 mg modified release tablet, 20**

| 8525Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 15.03 | 16.24 | [a] APO-Tramadol SR [TX]<br>[a] GA Tramadol SR 200mg [ED]<br>[a] Tramadol AN SR [EA]<br>[a] Tramadol SR generichealth [GQ]<br>[a] Zydol SR 200 [RW] | [a] Chem mart Tramadol SR [CH]<br>[a] Terry White Chemists Tramadol SR [TW]<br>[a] Tramadol Sandoz SR [SZ]<br>[a] Tramedo SR 200 [AF] |
| | | | [B]6.08 | 21.11 | 16.24 | [a] Tramal SR 200 [CS] | |

## ▪ TRAMADOL

**Restricted benefit**

Acute pain

**Clinical criteria:**

- The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

**Restricted benefit**

Chronic pain

Treatment Phase: Dose titration

**Clinical criteria:**

- The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

**tramadol hydrochloride 50 mg capsule, 20**

| 5232J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 13.09 | 14.30 | [a] APO-Tramadol [TX]<br>[a] Terry White Chemists Tramadol [TW]<br>[a] Tramadol AMNEAL [EF]<br>[a] Tramadol Sandoz [SZ]<br>[a] Tramedo [AF] | [a] Chem mart Tramadol [CH]<br>[a] Tramadol Actavis [ED]<br>[a] Tramadol AN [EA]<br>[a] Tramadol SCP [CR]<br>[a] Zydol [RW] |
| | | | [B]2.42 | 15.51 | 14.30 | [a] Tramal [CS] | |

## ▪ TRAMADOL

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

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

**Restricted benefit**

Acute pain

**Clinical criteria:**

- The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

**tramadol hydrochloride 50 mg capsule, 20**

| 8455B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 13.09 | 14.30 | [a] APO-Tramadol [TX]<br>[a] Terry White Chemists Tramadol [TW] | [a] Chem mart Tramadol [CH]<br>[a] Tramadol Actavis [ED] |

| | | | | | |
|---|---|---|---|---|---|
| | | | | [a] Tramadol AMNEAL [EF] | [a] Tramadol AN [EA] |
| | | | | [a] Tramadol Sandoz [SZ] | [a] Tramadol SCP [CR] |
| | | | | [a] Tramedo [AF] | [a] Zydol [RW] |
| [B]2.42 | 15.51 | 14.30 | | [a] Tramal [CS] | |

## ▪ TRAMADOL

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

**Restricted benefit**
Acute pain
**Clinical criteria:**
- The treatment must be for the short-term.

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

8582Q (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 13.94 | 15.15 | [a] Tramadol ACT [EA] | [a] Tramadol Sandoz [SZ] |
| | | | | | [a] Tramal 100 [CS] | |

## ▪ TRAMADOL

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

**Restricted benefit**
Chronic pain
Treatment Phase: Dose titration
**Clinical criteria:**
- The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

**tramadol hydrochloride 50 mg capsule, 20**

8611F (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 13.09 | 14.30 | [a] APO-Tramadol [TX] | [a] Chem mart Tramadol [CH] |
| | | | | | [a] Terry White Chemists Tramadol [TW] | [a] Tramadol Actavis [ED] |
| | | | | | [a] Tramadol AMNEAL [EF] | [a] Tramadol AN [EA] |
| | | | | | [a] Tramadol Sandoz [SZ] | [a] Tramadol SCP [CR] |
| | | | | | [a] Tramedo [AF] | [a] Zydol [RW] |
| [B]2.42 | 15.51 | 14.30 | | | [a] Tramal [CS] | |

# OTHER ANALGESICS AND ANTIPYRETICS

*Salicylic acid and derivatives*

## ▪ ASPIRIN

**Restricted benefit**
For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**aspirin 300 mg effervescent tablet, 96**

1010E (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 12.61 | 13.82 | Solprin [RC] |

## ▪ ASPIRIN

**Restricted benefit**
For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**aspirin 300 mg effervescent tablet, 96**

5018D (DP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 12.61 | 13.82 | Solprin [RC] |

*Anilides*

## ▪ PARACETAMOL

**Restricted benefit**
For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**paracetamol 240 mg/5 mL oral liquid, 200 mL**

1770E (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 14.79 | 16.00 | Panamax 240 Elixir [SW] |

**paracetamol 120 mg/5 mL oral liquid, 100 mL**

1747Y (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 13.66 | 14.87 | Panamax [SW] |

**paracetamol 500 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1746X NP | 1 | 1 | .. | 12.74 | 13.95 | [a] APO-Paracetamol [TX]<br>[a] Generic Health Pty Ltd [GQ]<br>[a] Paracetamol (Sandoz) [SZ]<br>[a] Parapane [AF] | [a] Febridol [EA]<br>[a] Panamax [SW]<br>[a] Paralgin [OW] |

## ▪ PARACETAMOL

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**paracetamol 240 mg/5 mL oral liquid, 200 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3349G DP | ‡1 | .. | .. | 14.79 | 16.00 | Panamax 240 Elixir [SW] |

**paracetamol 120 mg/5 mL oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3348F DP | ‡1 | .. | .. | 13.66 | 14.87 | Panamax [SW] |

**paracetamol 500 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5196L DP | 1 | .. | .. | 12.74 | 13.95 | [a] APO-Paracetamol [TX]<br>[a] Generic Health Pty Ltd [GQ]<br>[a] Paracetamol (Sandoz) [SZ]<br>[a] Parapane [AF] | [a] Febridol [EA]<br>[a] Panamax [SW]<br>[a] Paralgin [OW] |

## ▪ PARACETAMOL

**Restricted benefit**

Chronic arthropathies

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**paracetamol 500 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5224Y DP | 3 | .. | .. | *16.03 | 17.24 | [a] APO-Paracetamol [TX]<br>[a] Generic Health Pty Ltd [GQ]<br>[a] Paracetamol (Sandoz) [SZ]<br>[a] Parapane [AF] | [a] Febridol [EA]<br>[a] Panamax [SW]<br>[a] Paralgin [OW] |

## ▪ PARACETAMOL

**Restricted benefit**

Chronic arthropathies

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**paracetamol 500 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8784H NP | 3 | 4 | .. | *16.03 | 17.24 | [a] APO-Paracetamol [TX]<br>[a] Generic Health Pty Ltd [GQ]<br>[a] Paracetamol (Sandoz) [SZ]<br>[a] Parapane [AF] | [a] Febridol [EA]<br>[a] Panamax [SW]<br>[a] Paralgin [OW] |

## ▪ PARACETAMOL

**Note** Pharmaceutical benefits that have the form paracetamol 665 mg tablet: modified release, 96 and pharmaceutical benefits that have the form paracetamol 665 mg tablet: modified release, 192 are equivalent for the purposes of substitution.

**Restricted benefit**

Persistent pain

**Clinical criteria:**

- The condition must be associated with osteoarthritis.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**paracetamol 665 mg modified release tablet, 96**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8814X NP | 2 | 5 | .. | *18.55 | 19.76 | [a] APOHEALTH Osteo Relief Paracetamol 665 mg [TX] | [a] Osteomol 665 Paracetamol [CR] |

**paracetamol 665 mg tablet: modified release, 192**

| 10797G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 18.55 | 19.76 | [a] Osteomol 665 Paracetamol [CR] |

*Other analgesics and antipyretics*

## ▪ PREGABALIN

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

**Authority required (STREAMLINED)**
***4172***
Neuropathic pain
**Clinical criteria:**
- The condition must be refractory to treatment with other drugs.

**pregabalin 300 mg capsule, 56**

| 2363J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 76.58 | 38.80 | [a] APO-Pregabalin [TX]<br>[a] Lyrica [PF]<br>[a] Pregabalin APOTEX [GX]<br>[a] Pregabalin GH [GQ]<br>[a] Pregabalin-Teva [TB] | [a] LYPRALIN [RW]<br>[a] Lyzalon [AF]<br>[a] PREGABALIN-DRLA [RZ]<br>[a] Pregabalin Sandoz [SZ] |

**pregabalin 150 mg capsule, 56**

| 2355Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 54.98 | 38.80 | [a] APO-Pregabalin [TX]<br>[a] Lyrica [PF]<br>[a] Pregabalin APOTEX [GX]<br>[a] Pregabalin GH [GQ]<br>[a] Pregabalin-Teva [TB] | [a] LYPRALIN [RW]<br>[a] Lyzalon [AF]<br>[a] PREGABALIN-DRLA [RZ]<br>[a] Pregabalin Sandoz [SZ] |

**pregabalin 75 mg capsule, 56**

| 2335X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 39.70 | 38.80 | [a] APO-Pregabalin [TX]<br>[a] Lyrica [PF]<br>[a] Pregabalin APOTEX [GX]<br>[a] Pregabalin GH [GQ]<br>[a] Pregabalin-Teva [TB] | [a] LYPRALIN [RW]<br>[a] Lyzalon [AF]<br>[a] PREGABALIN-DRLA [RZ]<br>[a] Pregabalin Sandoz [SZ] |

**pregabalin 25 mg capsule, 56**

| 2348N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 24.02 | 25.23 | [a] APO-Pregabalin [TX]<br>[a] Lyrica [PF]<br>[a] Pregabalin APOTEX [GX]<br>[a] Pregabalin GH [GQ]<br>[a] Pregabalin-Teva [TB] | [a] LYPRALIN [RW]<br>[a] Lyzalon [AF]<br>[a] PREGABALIN-DRLA [RZ]<br>[a] Pregabalin Sandoz [SZ] |

## ANTIMIGRAINE PREPARATIONS

*Selective serotonin (5HT1) agonists*

## ▪ ELETRIPTAN

**Caution** Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

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

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

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

**Restricted benefit**
Migraine attack
**Clinical criteria:**
- The condition must have usually failed to respond to analgesics in the past.

**eletriptan 80 mg tablet, 4**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5291L NP | 1 | 5 | .. | 26.24 | 27.45 | Relpax [PF] |

**eletriptan 40 mg tablet, 4**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5290K NP | 1 | 5 | .. | 26.24 | 27.45 | Relpax [PF] |

## ▪ NARATRIPTAN

**Caution** Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

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

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

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

**Authority required**
Migraine attack
**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past.

**naratriptan 2.5 mg tablet, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8298R NP | 2 | 5 | $^{S}$2.28 | *29.47 | 28.40 | Naramig [AS] |

## ▪ NARATRIPTAN

**Caution** Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

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

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

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

**Authority required**
Migraine attack
**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom adverse events have occurred with other suitable PBS-listed drugs.

**Authority required**
Migraine attack
**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom drug interactions have occurred with other suitable PBS-listed drugs.

**Authority required**
Migraine attack
**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom drug interactions are expected to occur with other suitable PBS-listed drugs.

**Authority required**
Migraine attack
**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance.

**Authority required**
Migraine attack
**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences.

**naratriptan 2.5 mg tablet, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9734H NP | 2 | 5 | .. | *29.47 | 30.68 | Naramig [AS] |

## ▪ RIZATRIPTAN

**Caution** Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

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

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

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

**Note** Pharmaceutical benefits that have the form rizatriptan wafer 10 mg (as benzoate) and pharmaceutical benefits that have the form rizatriptan tablet (orally disintegrating) 10 mg (as benzoate) are equivalent for the purposes of substitution.

**Restricted benefit**
Migraine attack
**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past.

### rizatriptan 10 mg wafer, 2

| 9313E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *20.91 | 22.12 | [a] Maxalt [AL] | [a] Rizatriptan Wafers-10mg [AF] |

### rizatriptan 10 mg orally disintegrating tablet, 2

| 10551H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *20.91 | 22.12 | [a] APO-Rizatriptan [TX]<br>[a] MAXATAN [RW]<br>[a] Rizatriptan ODT GH [GQ] | [a] Chem mart Rizatriptan [CH]<br>[a] Rizatriptan AN ODT [EA]<br>[a] Terry White Chemists Rizatriptan [TW] |

## ▪ SUMATRIPTAN

**Caution** Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

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

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

**Note** Pharmaceutical benefits that have the form sumatriptan tablet 50 mg (as succinate) and pharmaceutical benefits that have the form sumatriptan tablet (fast disintegrating) 50 mg (as succinate) are equivalent for the purposes of substitution.

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

**Restricted benefit**
Migraine attack
**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past.

### sumatriptan 20 mg/actuation nasal spray, 2 x 1 actuation

| 8341B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 22.25 | 23.46 | Imigran [AS] |

### SUMATRIPTAN Tablet (fast disintegrating) 50 mg (as succinate), 2

| 8885P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | [B]4.20 | *20.45 | 17.46 | [a] Imigran FDT [AS] |

### SUMATRIPTAN Tablet 50 mg (as succinate), 2

| 8144P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *16.25 | 17.46 | [a] APO-Sumatriptan [TX]<br>[a] Iptam [AL]<br>[a] Sumatriptan Sandoz [SZ] | [a] Chem mart Sumatriptan [CH]<br>[a] Sumatran [OW]<br>[a] Terry White Chemists Sumatriptan [TW] |
| | | | [B]4.20 | *20.45 | 17.46 | [a] Imigran [LN] | |

### sumatriptan 50 mg tablet, 4

| 1849H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.25 | 17.46 | [a] APO-Sumatriptan [TX]<br>[a] Iptam [AL]<br>[a] Sumatran [OW]<br>[a] Sumatriptan generichealth [GQ] | [a] Chem mart Sumatriptan [CH]<br>[a] Pharmacor Sumatriptan 50 [CR]<br>[a] Sumatriptan AN [EA]<br>[a] Sumatriptan RBX [RA] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Sumatriptan Sandoz [SZ] | [a] Terry White Chemists Sumatriptan [TW] |
| | | | [B]4.19 | 20.44 | 17.46 | [a] Imigran [LN] | |

**SUMATRIPTAN Tablet 50 mg (base) (fast disintegrating), 4**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10694W NP | 1 | 5 | [B]4.19 | 20.44 | 17.46 | [a] Imigran FDT [AS] |

## ▪ ZOLMITRIPTAN

**Caution** Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

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

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

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

**Restricted benefit**
Migraine attack
**Clinical criteria:**
- The condition must have usually failed to respond to analgesics in the past.

**zolmitriptan 2.5 mg tablet, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8266C NP | 2 | 5 | .. | *22.97 | 24.18 | [a] APO-Zolmitriptan [TX] | [a] Zoltrip [RW] |
| | | | [B]2.14 | *25.11 | 24.18 | [a] Zomig [AP] | |

*Other antimigraine preparations*

## ▪ CYPROHEPTADINE

**Note** Cyproheptadine hydrochloride is not PBS-subsidised for use in hay fever or atopy.

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

**Restricted benefit**
Prevention of migraine

**cyproheptadine hydrochloride 4 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1798P NP | 1 | 2 | .. | 17.52 | 18.73 | Periactin [AS] |

## ▪ PIZOTIFEN

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

**pizotifen 500 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3074T NP | 1 | 2 | .. | 24.67 | 25.88 | Sandomigran 0.5 [AE] |

# ▪ ANTIEPILEPTICS

## ANTIEPILEPTICS

*Barbiturates and derivatives*

## ▪ PHENOBARBITONE

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

**Restricted benefit**
Epilepsy

**phenobarbitone sodium 219 mg/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2138M NP | 1 | .. | .. | 38.02 | 38.80 | Fawns and McAllan Proprietary Limited [FM] |

**phenobarbitone 30 mg tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1850J NP | 1 | 4 | .. | 19.50 | 20.71 | Phenobarb [RW] |

## ▪ PRIMIDONE

**Note Continuing Therapy Only:**

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

**primidone 250 mg tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1939C NP | 1 | 2 | .. | 77.64 | 38.80 | Mysoline [LM] |

*Hydantoin derivatives*

## ▪ PHENYTOIN

**Note Continuing Therapy Only:**

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

**phenytoin sodium 100 mg capsule, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1874P NP | 1 | 2 | .. | 34.85 | 36.06 | Dilantin Sodium [PF] |

**phenytoin sodium 30 mg capsule, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1873N NP | 1 | 2 | .. | 31.08 | 32.29 | Dilantin Sodium [PF] |

**phenytoin 30 mg/5 mL oral liquid, 500 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2692Q NP | ‡1 | 3 | .. | 30.81 | 32.02 | Dilantin [PF] |

**phenytoin 50 mg chewable tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1249R NP | 1 | 2 | .. | 48.49 | 38.80 | Dilantin Infatabs [PF] |

*Succinimide derivatives*

## ▪ ETHOSUXIMIDE

**Note Continuing Therapy Only:**

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

**ethosuximide 250 mg/5 mL oral liquid, 200 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1414K NP | ‡1 | 5 | .. | 29.81 | 31.02 | Zarontin [IX] |

**ethosuximide 250 mg capsule, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1413J NP | 1 | 2 | .. | 76.27 | 38.80 | Zarontin [IX] |

*Benzodiazepine derivatives*

## ▪ CLONAZEPAM

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Epilepsy

**clonazepam 1 mg/mL injection [5 x 1 mL ampoules] (&) inert substance diluent [5 x 1 mL ampoules], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1807D NP | 1 | .. | .. | 21.66 | 22.87 | Rivotril [RO] |

## ▪ CLONAZEPAM

**Caution** Abuse of clonazepam has been reported. Refer to the current product information.

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

**Authority required**
Epilepsy
**Clinical criteria:**
- The condition must be neurologically proven.

### clonazepam 500 microgram tablet, 100

| 1805B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | .. | *22.47 | 23.68 | [a] Paxam 0.5 [AF] |
| | | | [B]3.68 | *26.15 | 23.68 | [a] Rivotril [RO] |

### clonazepam 2 mg tablet, 100

| 1806C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | .. | *32.51 | 33.72 | [a] Paxam 2 [AF] |
| | | | [B]4.60 | *37.11 | 33.72 | [a] Rivotril [RO] |

### clonazepam 2.5 mg/mL oral liquid, 10 mL

| 1808E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *18.59 | 19.80 | Rivotril [RO] |

## ▪ NITRAZEPAM

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

**Authority required**
Myoclonic epilepsy
**Authority required**
Malignant neoplasia (late stage)
**Authority required**
Insomnia
**Clinical criteria:**
- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority required**
Insomnia
**Clinical criteria:**
- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

### nitrazepam 5 mg tablet, 25

| 2732T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *14.31 | 15.52 | [a] Alodorm [AF] |
| | | | [B]2.48 | *16.79 | 15.52 | [a] Mogadon [IA] |

*Carboxamide derivatives*

## ▪ CARBAMAZEPINE

### CARBAMAZEPINE Tablet 200 mg, 100

| 1724R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 2 | .. | .. | *30.73 | 31.94 | [a] Carbamazepine Sandoz [SZ] |
| | | | [B]2.96 | *33.69 | 31.94 | [a] Tegretol 200 [NV] |

### CARBAMAZEPINE Tablet 100 mg, 100

| 5039F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 2 | .. | .. | *22.85 | 24.06 | [a] Carbamazepine Sandoz [SZ] |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | [B]3.00 | *25.85 | 24.06 | [a] Tegretol 100 [NV] |

**carbamazepine 400 mg modified release tablet, 200**

| 5037D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 49.20 | 38.80 | Tegretol CR 400 [NV] |

**carbamazepine 100 mg/5 mL oral liquid, 300 mL**

| 5041H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | ‡1 | .. | .. | 24.07 | 25.28 | Tegretol Liquid [NV] |

**carbamazepine 200 mg modified release tablet, 200**

| 5038E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 31.14 | 32.35 | Tegretol CR 200 [NV] |

## ▪ CARBAMAZEPINE

**Note Continuing Therapy Only:**

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

**CARBAMAZEPINE Tablet 200 mg, 100**

| 1706T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | .. | *30.73 | 31.94 | [a] Carbamazepine Sandoz [SZ] |
| | | | [B]2.96 | *33.69 | 31.94 | [a] Tegretol 200 [NV] |

**CARBAMAZEPINE Tablet 100 mg, 100**

| 2422L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | .. | *22.85 | 24.06 | [a] Carbamazepine Sandoz [SZ] |
| | | | [B]3.00 | *25.85 | 24.06 | [a] Tegretol 100 [NV] |

**carbamazepine 400 mg modified release tablet, 200**

| 2431Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 49.20 | 38.80 | Tegretol CR 400 [NV] |

**carbamazepine 100 mg/5 mL oral liquid, 300 mL**

| 2427R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 24.07 | 25.28 | Tegretol Liquid [NV] |

**carbamazepine 200 mg modified release tablet, 200**

| 2426Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 31.14 | 32.35 | Tegretol CR 200 [NV] |

## ▪ OXCARBAZEPINE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***5183***

Seizures

**Clinical criteria:**

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**oxcarbazepine 300 mg tablet, 100**

| 8585W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 104.93 | 38.80 | Trileptal [NV] |

**oxcarbazepine 60 mg/mL oral liquid, 250 mL**

| 8588B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *124.83 | 38.80 | Trileptal [NV] |

**oxcarbazepine 600 mg tablet, 100**

| 8586X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 167.89 | 38.80 | Trileptal [NV] |

**oxcarbazepine 150 mg tablet, 100**

| 8584T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 67.96 | 38.80 | Trileptal [NV] |

*Fatty acid derivatives*

## ▪ TIAGABINE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***4928***
Partial epileptic seizures
**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**tiagabine 15 mg tablet, 50**

| 8223T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *175.57 | 38.80 | Gabitril [OA] |

**tiagabine 5 mg tablet, 50**

| 8221Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *68.27 | 38.80 | Gabitril [OA] |

**tiagabine 10 mg tablet, 50**

| 8222R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *125.45 | 38.80 | Gabitril [OA] |

## ▪ VALPROATE

**Caution** There are reports of fatal hepatotoxicity, particularly in children.
There is increasing evidence of dose-related teratogenesis from this drug.

**Note** Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**valproate sodium 200 mg/5 mL oral liquid, 300 mL**

| 2293Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | .. | *39.05 | 38.80 | Epilim Liquid [SW] |

**valproate sodium 200 mg/5 mL oral liquid, 300 mL**

| 2295T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | .. | *39.05 | 38.80 | Epilim Syrup [SW] |

**valproate sodium 100 mg tablet, 100**

| 2294R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | .. | *33.33 | 34.54 | Epilim [SW] |

**valproate sodium 200 mg enteric tablet, 100**

| 2289L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | .. | *22.83 | 24.04 | [a] Sodium Valproate Sandoz [SZ]<br>[a] Valpro 200 [AF] | [a] Valprease 200 [RW]<br>[a] Valproate Winthrop EC 200 [WA] |
| | | | [B]2.00 | *24.83 | 24.04 | [a] Epilim EC [SW] | |

**valproate sodium 500 mg enteric tablet, 100**

| 2290M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | .. | *34.33 | 35.54 | [a] Sodium Valproate Sandoz [SZ]<br>[a] Valpro 500 [AF] | [a] Valprease 500 [RW]<br>[a] Valproate Winthrop EC 500 [WA] |
| | | | [B]2.00 | *36.33 | 35.54 | [a] Epilim EC [SW] | |

## ▪ VIGABATRIN

**Caution** Visual field defects have been reported with this drug.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4929***

Epileptic seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**vigabatrin 500 mg tablet, 100**

| 2667J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 108.13 | 38.80 | Sabril [SW] |

**vigabatrin 500 mg powder for oral liquid, 60 sachets**

| 2668K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 73.90 | 38.80 | Sabril [SW] |

*Other antiepileptics*

## ▪ GABAPENTIN

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4928***

Partial epileptic seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**gabapentin 100 mg capsule, 100**

| 8505P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.13 | 16.34 | [a] APO-Gabapentin [TX]<br>[a] Gabapentin Aspen 100 [RW]<br>[a] Neurontin [PF] | [a] Gabacor [CR]<br>[a] GAPENTIN [RF]<br>[a] Nupentin 100 [AF] |

**gabapentin 400 mg capsule, 100**

| 1835N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 29.50 | 30.71 | [a] Gabacor [CR]<br>[a] Gabapentin Aspen 400 [RW]<br>[a] Gabapentin Sandoz [SZ]<br>[a] Neurontin [PF] | [a] Gabapentin AN [EA]<br>[a] Gabapentin GH [GQ]<br>[a] GenRx Gabapentin [GX]<br>[a] Nupentin 400 [AF] |

**gabapentin 600 mg tablet, 100**

| 8559L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 40.31 | 38.80 | [a] Gabapentin AN [EA]<br>[a] GAPENTIN [RF]<br>[a] Neurontin [PF]<br>[a] Pharmacor Gabapentin 600 [CR] | [a] Gabapentin Aspen 600 [RW]<br>[a] GenRx Gabapentin [GX]<br>[a] Nupentin Tabs [AF] |

**gabapentin 300 mg capsule, 100**

| 1834M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 24.59 | 25.80 | [a] Gabacor [CR]<br>[a] Gabapentin Aspen 300 [RW]<br>[a] Gabapentin Sandoz [SZ]<br>[a] GenRx Gabapentin [GX]<br>[a] Nupentin 300 [AF] | [a] Gabapentin AN [EA]<br>[a] Gabapentin GH [GQ]<br>[a] GAPENTIN [RF]<br>[a] Neurontin [PF] |

**gabapentin 800 mg tablet, 100**

| 8389M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 50.06 | 38.80 | [a] Gabapentin AN [EA]<br>[a] GAPENTIN [RF]<br>[a] Neurontin [PF]<br>[a] Pharmacor Gabapentin 800 [CR] | [a] Gabapentin Aspen 800 [RW]<br>[a] GenRx Gabapentin [GX]<br>[a] Nupentin Tabs [AF] |

## ▪ LACOSAMIDE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4271***

Intractable partial epileptic seizures

Treatment Phase: Initial

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents, **AND**
- The treatment must be for dose titration purposes.

**Population criteria:**

- Patient must be aged 16 years or older.

**lacosamide 50 mg tablet, 14**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9333F NP | 1 | 1 | .. | 30.74 | 31.95 | Vimpat [UC] |

**lacosamide 150 mg tablet, 14**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9336J NP | 1 | 1 | .. | 70.04 | 38.80 | Vimpat [UC] |

**lacosamide 100 mg tablet, 14**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9334G NP | 1 | 1 | .. | 50.40 | 38.80 | Vimpat [UC] |

## ▪ LACOSAMIDE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4249***

Intractable partial epileptic seizures

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously been treated with PBS-subsidised lacosamide.

**Population criteria:**

- Patient must be aged 16 years or older.

**lacosamide 50 mg tablet, 14**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10293R NP | 4 | 5 | .. | *89.71 | 38.80 | Vimpat [UC] |

## ▪ LACOSAMIDE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4264***

Intractable partial epileptic seizures

Treatment Phase: Initial

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

**Population criteria:**

- Patient must be aged 16 years or older.

**Authority required (STREAMLINED)**

***4249***

Intractable partial epileptic seizures

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously been treated with PBS-subsidised lacosamide.

**Population criteria:**

- Patient must be aged 16 years or older.

**lacosamide 100 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9335H NP | 1 | 5 | .. | 168.33 | 38.80 | Vimpat [UC] |

## ▪ LACOSAMIDE

**Note** No applications for increased maximum quantities will be authorised for the 56 tablet packs of the 150 mg and 200 mg strengths.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4240***

Intractable partial epileptic seizures

Treatment Phase: Initial

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

**Population criteria:**

- Patient must be aged 16 years or older.

**Authority required (STREAMLINED)**

***4257***

Intractable partial epileptic seizures

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously been treated with PBS-subsidised lacosamide.

**Population criteria:**

- Patient must be aged 16 years or older.

**lacosamide 200 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9338L NP | 1 | 5 | .. | 330.20 | 38.80 | Vimpat [UC] |

**lacosamide 150 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9337K NP | 1 | 5 | .. | 248.85 | 38.80 | Vimpat [UC] |

## ▪ LAMOTRIGINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***5138***

Epileptic seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**lamotrigine 200 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2851C NP | 1 | 5 | .. | 37.06 | 38.27 | [a] APO-Lamotrigine [TX]<br>[a] LAMITAN [RF]<br>[a] Lamotrigine Aspen 200 [RW]<br>[a] Lamotrigine GH [GQ]<br>[a] Logem [AL] | [a] Lamidus [RA]<br>[a] Lamotrigine AN [EA]<br>[a] Lamotrigine generichealth [HQ]<br>[a] Lamotrigine Sandoz [SZ]<br>[a] Reedos 200 [DO] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | [B]1.49 | 38.55 | 38.27 | [a] Lamictal [AS] | |

**lamotrigine 100 mg tablet, 56**

| 2850B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 26.54 | 27.75 | [a] APO-Lamotrigine [TX]<br>[a] LAMITAN [RF]<br>[a] Lamotrigine Aspen 100 [RW]<br>[a] Lamotrigine GH [GQ]<br>[a] Logem [AL] | [a] Lamidus [RA]<br>[a] Lamotrigine AN [EA]<br>[a] Lamotrigine generichealth [HQ]<br>[a] Lamotrigine Sandoz [SZ]<br>[a] Reedos 100 [DO] |
| | | | [B]1.51 | 28.05 | 27.75 | [a] Lamictal [AS] | |

**lamotrigine 50 mg tablet, 56**

| 2849Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 20.37 | 21.58 | [a] APO-Lamotrigine [TX]<br>[a] LAMITAN [RF]<br>[a] Lamotrigine Aspen 50 [RW]<br>[a] Lamotrigine Sandoz [SZ]<br>[a] Reedos 50 [DO] | [a] Lamidus [RA]<br>[a] Lamotrigine AN [EA]<br>[a] Lamotrigine GH [GQ]<br>[a] Logem [AL] |
| | | | [B]1.44 | 21.81 | 21.58 | [a] Lamictal [AS] | |

**lamotrigine 25 mg tablet, 56**

| 2848X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.66 | 17.87 | [a] APO-Lamotrigine [TX]<br>[a] LAMITAN [RF]<br>[a] Lamotrigine Aspen 25 [RW]<br>[a] Lamotrigine Sandoz [SZ]<br>[a] Reedos 25 [DO] | [a] Lamidus [RA]<br>[a] Lamotrigine AN [EA]<br>[a] Lamotrigine GH [GQ]<br>[a] Logem [AL] |
| | | | [B]1.61 | 18.27 | 17.87 | [a] Lamictal [AS] | |

**lamotrigine 5 mg tablet, 56**

| 8063J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.41 | 18.62 | [a] Lamictal [AS] | [a] Lamotrigine Aspen 5 [RW] |

## ▪ LEVETIRACETAM

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4928***

Partial epileptic seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**levetiracetam 250 mg tablet, 60**

| 8654L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 22.62 | 23.83 | [a] APO-Levetiracetam [TX]<br>[a] Keppra [UC]<br>[a] Kevtam [AF]<br>[a] Levecetam 250 [RZ]<br>[a] Levetiracetam GH [GQ]<br>[a] Levi 250 [RW] | [a] Kepcet [ED]<br>[a] Kerron 250 [DO]<br>[a] Levactam [ER]<br>[a] Levetiracetam AN [EA]<br>[a] Levetiracetam SZ [SZ] |

**levetiracetam 1 g tablet, 60**

| 8656N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 43.09 | 38.80 | [a] APO-Levetiracetam [TX]<br>[a] Keppra [UC]<br>[a] Kevtam 1000 [AF]<br>[a] Levecetam 1000 [RZ]<br>[a] Levetiracetam GH [GQ]<br>[a] Levi 1000 [RW] | [a] Kepcet [ED]<br>[a] Kerron 1000 [DO]<br>[a] Levactam [ER]<br>[a] Levetiracetam AN [EA]<br>[a] Levetiracetam SZ [SZ]<br>[a] Levitaccord [RA] |

**levetiracetam 500 mg tablet, 60**

| 8655M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 30.29 | 31.50 | [a] APO-Levetiracetam [TX]<br>[a] Keppra [UC]<br>[a] Kevtam [AF]<br>[a] Levecetam 500 [RZ] | [a] Kepcet [ED]<br>[a] Kerron 500 [DO]<br>[a] Levactam [ER]<br>[a] Levetiracetam AN [EA] |

[a] Levetiracetam GH [GQ] [a] Levetiracetam SZ [SZ]
[a] Levi 500 [RW]

## ▪ LEVETIRACETAM

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***5215***
Partial epileptic seizures
**Clinical criteria:**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, **AND**
- Patient must be unable to take a solid dose form of levetiracetam.

### levetiracetam 100 mg/mL oral liquid, 300 mL

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9169N NP | ‡1 | 5 | .. | 73.45 | 38.80 | [a] APO-Levetiracetam [TX]<br>[a] Kerron [DO] | [a] Keppra [UC]<br>[a] Levetiracetam-AFT [AE] |

## ▪ PERAMPANEL

**Authority required (STREAMLINED)**
***4656***
Intractable partial epileptic seizures
Treatment Phase: Initial
**Clinical criteria:**
- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

**Treatment criteria:**
- Must be treated by a neurologist.

### perampanel 2 mg tablet, 7

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10157N | 2 | 1 | .. | *52.47 | 38.80 | Fycompa [EI] |

## ▪ PERAMPANEL

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***4658***
Intractable partial epileptic seizures
Treatment Phase: Continuing
**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug.

### perampanel 8 mg tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10160R NP | 1 | 5 | .. | 347.33 | 38.80 | Fycompa [EI] |

### perampanel 10 mg tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10151G NP | 1 | 5 | .. | 347.33 | 38.80 | Fycompa [EI] |

### perampanel 6 mg tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10163X NP | 1 | 5 | .. | 261.72 | 38.80 | Fycompa [EI] |

### perampanel 12 mg tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10159Q NP | 1 | 5 | .. | 347.33 | 38.80 | Fycompa [EI] |

**perampanel 4 mg tablet, 28**

| 10162W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 176.58 | 38.80 | Fycompa [EI] |

## ▪ SULTHIAME

**Note** Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**sulthiame 50 mg tablet, 200**

| 2099L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 76.77 | 38.80 | Ospolot [PL] |

**sulthiame 200 mg tablet, 200**

| 2100M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 183.58 | 38.80 | Ospolot [PL] |

## ▪ TOPIRAMATE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***5516***
Seizures
**Clinical criteria:**

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**topiramate 100 mg tablet, 60**

| 8165R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 28.58 | 29.79 | [a] APO-Topiramate [TX] | [a] Epiramax 100 [RW] |
| | | | | | | [a] RBX Topiramate [RA] | [a] Tamate [AF] |
| | | | | | | [a] Topamax [JC] | [a] Topiramate AN [EA] |
| | | | | | | [a] Topiramate GH [GQ] | [a] Topiramate Sandoz [SZ] |

**topiramate 200 mg tablet, 60**

| 8166T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 40.48 | 38.80 | [a] APO-Topiramate [TX] | [a] Epiramax 200 [RW] |
| | | | | | | [a] RBX Topiramate [RA] | [a] Tamate [AF] |
| | | | | | | [a] Topamax [JC] | [a] Topiramate AN [EA] |
| | | | | | | [a] Topiramate GH [GQ] | [a] Topiramate Sandoz [SZ] |

## ▪ TOPIRAMATE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***5173***
Seizures
**Clinical criteria:**

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, **AND**
- Patient must be unable to take a solid dose form of topiramate.

**topiramate 15 mg capsule, 60**

| 8371N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 19.18 | 20.39 | Topamax Sprinkle [JC] |

**topiramate 25 mg capsule, 60**

| 8372P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.75 | 18.96 | Topamax Sprinkle [JC] |

**topiramate 50 mg capsule, 60**

| 8520K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 22.19 | 23.40 | Topamax Sprinkle [JC] |

## ▪ TOPIRAMATE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***5516***

Seizures

**Clinical criteria:**

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**Authority required (STREAMLINED)**

***5325***

Migraine

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must have experienced an average of 3 or more migraines per month over a period of at least 6 months, **AND**
- Patient must have a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; OR
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker, **AND**
- Patient must have a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk; OR
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with pizotifen.

Details of the contraindication and/or intolerance(s) must be documented in the patient's medical records when treatment is initiated.

**topiramate 50 mg tablet, 60**

| 8164Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 22.21 | 23.42 | [a] APO-Topiramate [TX]<br>[a] RBX Topiramate [RA]<br>[a] Topamax [JC]<br>[a] Topiramate GH [GQ] | [a] Epiramax 50 [RW]<br>[a] Tamate [AF]<br>[a] Topiramate AN [EA]<br>[a] Topiramate Sandoz [SZ] |

**topiramate 25 mg tablet, 60**

| 8163P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.86 | 19.07 | [a] APO-Topiramate [TX]<br>[a] RBX Topiramate [RA]<br>[a] Topamax [JC]<br>[a] Topiramate GH [GQ] | [a] Epiramax 25 [RW]<br>[a] Tamate [AF]<br>[a] Topiramate AN [EA]<br>[a] Topiramate Sandoz [SZ] |

## ▪ ZONISAMIDE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4928***

Partial epileptic seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**zonisamide 100 mg capsule, 56**

| 9390F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *74.23 | 38.80 | [a] APO-Zonisamide [TX] | [a] Zonegran [SA] |

**zonisamide 25 mg capsule, 56**

| 9388D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 22.45 | 23.66 | [a] APO-Zonisamide [TX] | [a] Zonegran [SA] |

**zonisamide 50 mg capsule, 56**

| 9389E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 30.04 | 31.25 | [a] APO-Zonisamide [TX] | [a] Zonegran [SA] |

## ANTI-PARKINSON DRUGS

### ANTICHOLINERGIC AGENTS

*Tertiary amines*

### BENZHEXOL

**benzhexol hydrochloride 5 mg tablet, 200**

| 1110K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 24.50 | 25.71 | Artane [RW] |

**benzhexol hydrochloride 2 mg tablet, 200**

| 1109J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 18.85 | 20.06 | Artane [RW] |

### BIPERIDEN

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**biperiden hydrochloride 2 mg tablet, 100**

| 2544X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | .. | *23.05 | 24.26 | Akineton [GH] |

*Ethers of tropine or tropine derivatives*

### BENZATROPINE

**benzatropine mesilate 2 mg/2 mL injection, 10 x 2 mL vials**

| 10013B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 263.28 | 38.80 | Benztropine Omega [FK] |

**benzatropine mesilate 2 mg/2 mL injection, 10 x 2 mL vials**

| 10027R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 263.28 | 38.80 | Benztropine Omega [FK] |

**benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL ampoules**

| 3038X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 95.01 | 38.80 | Cogentin [FK] |

**benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL ampoules**

| 5031T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 95.01 | 38.80 | Cogentin [FK] |

**benzatropine mesilate 2 mg tablet, 60**

| 2362H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 18.28 | 19.49 | Benztrop [PL] |

### DOPAMINERGIC AGENTS

*Dopa and dopa derivatives*

### LEVODOPA + BENSERAZIDE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**levodopa 50 mg + benserazide 12.5 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2227F NP | 1 | 5 | .. | 24.79 | 26.00 | Madopar 62.5 [RO] |

**levodopa 100 mg + benserazide 25 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2225D NP | 1 | 5 | .. | 37.94 | 38.80 | Madopar 125 [RO] |

**levodopa 200 mg + benserazide 50 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2228G NP | 1 | 5 | .. | 48.23 | 38.80 | Madopar [RO] |

**levodopa 100 mg + benserazide 25 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2229H NP | 1 | 5 | .. | 37.94 | 38.80 | Madopar 125 [RO] |

**LEVODOPA with BENSERAZIDE Dispersible tablet 100 mg-25 mg, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8219N NP | 1 | 5 | .. | 37.94 | 38.80 | Madopar Rapid 125 [RO] |

**levodopa 100 mg + benserazide 25 mg modified release capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2231K NP | 1 | 5 | .. | 40.61 | 38.80 | Madopar HBS [RO] |

**LEVODOPA with BENSERAZIDE Dispersible tablet 50 mg-12.5 mg, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8218M NP | 1 | 5 | .. | 24.79 | 26.00 | Madopar Rapid 62.5 [RO] |

**levodopa 200 mg + benserazide 50 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2226E NP | 1 | 5 | .. | 48.23 | 38.80 | Madopar [RO] |

## ▪ LEVODOPA + CARBIDOPA ANHYDROUS

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**levodopa 250 mg + carbidopa anhydrous 25 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1245M NP | 1 | 5 | .. | 45.26 | 38.80 | Sinemet [MK] |

**levodopa 100 mg + carbidopa anhydrous 25 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1242J NP | 1 | 5 | .. | 38.80 | 38.80 | [a] Kinson [AF] |
| | | | [B]4.85 | 43.65 | 38.80 | [a] Sinemet 100/25 [MK] |

## ▪ LEVODOPA + CARBIDOPA ANHYDROUS

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The condition must be one in which fluctuations in motor function are not adequately controlled by frequent dosing with conventional formulations of levodopa with decarboxylase inhibitor.

**levodopa 200 mg + carbidopa anhydrous 50 mg modified release tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1255C NP | 1 | 5 | .. | 66.95 | 38.80 | Sinemet CR [MK] |

## ▪ LEVODOPA + CARBIDOPA ANHYDROUS

**Note** Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***5473***

Advanced Parkinson disease

Treatment Phase: Maintenance therapy

**Clinical criteria:**

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- Patient must have been commenced on treatment in a hospital-based movement disorder clinic.

**levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL**

| 8970D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *11685.47 | 38.80 | Duodopa [VE] |

## ▪ LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- Patient must be being treated with levodopa decarboxylase inhibitor combinations, **AND**
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- Patient must be stabilised on concomitant treatment with levodopa decarboxylase inhibitor combinations and entacapone.

**levodopa 125 mg + carbidopa anhydrous 31.25 mg + entacapone 200 mg tablet, 100**

| 9345W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 4 | .. | *345.87 | 38.80 | Stalevo 125/31.25/200mg [NV] |

**levodopa 150 mg + carbidopa anhydrous 37.5 mg + entacapone 200 mg tablet, 100**

| 8799D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 4 | .. | *364.49 | 38.80 | Stalevo 150/37.5/200mg [NV] |

**levodopa 50 mg + carbidopa anhydrous 12.5 mg + entacapone 200 mg tablet, 100**

| 8797B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 4 | .. | *302.31 | 38.80 | Stalevo 50/12.5/200mg [NV] |

**levodopa 200 mg + carbidopa anhydrous 50 mg + entacapone 200 mg tablet, 100**

| 9292C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 4 | .. | *393.13 | 38.80 | Stalevo 200/50/200mg [NV] |

**levodopa 75 mg + carbidopa anhydrous 18.75 mg + entacapone 200 mg tablet, 100**

| 9344T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 4 | .. | *316.01 | 38.80 | Stalevo 75/18.75/200mg [NV] |

**levodopa 100 mg + carbidopa anhydrous 25 mg + entacapone 200 mg tablet, 100**

| 8798C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 4 | .. | *333.41 | 38.80 | Stalevo 100/25/200mg [NV] |

*Adamantane derivatives*

## ▪ AMANTADINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The condition must not be drug induced.

**amantadine hydrochloride 100 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3016R NP | 1 | 5 | .. | 42.81 | 38.80 | Symmetrel 100 [NV] |

*Dopamine agonists*

## ▪ BROMOCRIPTINE

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

Acromegaly

**Restricted benefit**

Parkinson disease

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom surgery is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had surgery for this condition with incomplete resolution.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom radiotherapy is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had radiotherapy for this condition with incomplete resolution.

**bromocriptine 2.5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1443Y | 2 | 5 | .. | *32.83 | 34.04 | Parlodel [SZ] |

## ▪ CABERGOLINE

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**cabergoline 2 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8394T NP | 1 | 5 | .. | 76.11 | 38.80 | Cabaser [PF] |

**cabergoline 1 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8393R NP | 1 | 5 | .. | 59.60 | 38.80 | Cabaser [PF] |

## ▪ PRAMIPEXOLE

**Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**pramipexole hydrochloride monohydrate 250 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9152Q NP | 1 | 5 | .. | 28.97 | 30.18 | [a] APO-Pramipexole [TX]<br>[a] Pramipexole GH [GQ] | [a] Pramipexole AN [EA]<br>[a] Sifrol [BY] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Simipex 0.25 [RW] | [a] Simpral [AF] |

**pramipexole hydrochloride monohydrate 125 microgram tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9151P NP | 1 | .. | .. | 13.82 | 15.03 | [a] APO-Pramipexole [TX]<br>[a] Pramipexole GH [GQ]<br>[a] Simipex 0.125 [RW] | [a] Pramipexole AN [EA]<br>[a] Sifrol [BY]<br>[a] Simpral [AF] |

**pramipexole hydrochloride monohydrate 1 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9153R NP | 1 | 5 | .. | 89.14 | 38.80 | [a] APO-Pramipexole [TX]<br>[a] Pramipexole GH [GQ]<br>[a] Simipex 1 [RW] | [a] Pramipexole AN [EA]<br>[a] Sifrol [BY]<br>[a] Simpral [AF] |

## ▪ PRAMIPEXOLE

**Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.
Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
Parkinson disease

**pramipexole hydrochloride monohydrate 1.5 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3420B NP | 1 | 5 | .. | 41.63 | 38.80 | [a] APO-Pramipexole ER [TX]<br>[a] Sifrol ER [BY] | [a] Pramipexole XR GP [AF]<br>[a] SIMIPEX XR [RW] |

**pramipexole hydrochloride monohydrate 2.25 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5143Q NP | 1 | 5 | .. | 56.89 | 38.80 | [a] APO-Pramipexole ER [TX]<br>[a] Sifrol ER [BY] | [a] Pramipexole XR GP [AF]<br>[a] SIMIPEX XR [RW] |

**pramipexole hydrochloride monohydrate 375 microgram modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3418X NP | 1 | 5 | .. | 18.85 | 20.06 | [a] APO-Pramipexole ER [TX]<br>[a] Sifrol ER [BY] | [a] Pramipexole XR GP [AF]<br>[a] SIMIPEX XR [RW] |

**pramipexole hydrochloride monohydrate 3.75 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5145T NP | 1 | 5 | .. | 92.98 | 38.80 | [a] APO-Pramipexole ER [TX]<br>[a] Sifrol ER [BY] | [a] Pramipexole XR GP [AF]<br>[a] SIMIPEX XR [RW] |

**pramipexole hydrochloride monohydrate 3 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3421C NP | 1 | 5 | .. | 77.72 | 38.80 | [a] APO-Pramipexole ER [TX]<br>[a] Sifrol ER [BY] | [a] Pramipexole XR GP [AF]<br>[a] SIMIPEX XR [RW] |

**pramipexole hydrochloride monohydrate 750 microgram modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3419Y NP | 1 | 5 | .. | 26.36 | 27.57 | [a] APO-Pramipexole ER [TX]<br>[a] Sifrol ER [BY] | [a] Pramipexole XR GP [AF]<br>[a] SIMIPEX XR [RW] |

**pramipexole hydrochloride monohydrate 4.5 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3422D NP | 1 | 5 | .. | 111.03 | 38.80 | [a] APO-Pramipexole ER [TX]<br>[a] Sifrol ER [BY] | [a] Pramipexole XR GP [AF]<br>[a] SIMIPEX XR [RW] |

## ▪ PRAMIPEXOLE

**Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.
Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note** This drug is not PBS-subsidised for Restless Legs Syndrome secondary to other causes

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Primary severe restless legs syndrome

**Clinical criteria:**

- Patient must manifest all 4 diagnostic criteria for Restless Legs Syndrome, **AND**
- Patient must have a baseline International Restless Legs Syndrome Rating Scale (IRLSRS) score greater than or equal to 21 points prior to initiation of pramipexole.

The date and IRLSRS score must be documented in the patient's medical records at the time pramipexole treatment is initiated.

The diagnostic criteria for Restless Legs Syndrome are:

(a) An urge to move the legs usually accompanied or caused by unpleasant sensations in the legs; and

(b) The urge to move or unpleasant sensations begin or worsen during periods of rest or inactivity such as lying or sitting; and

(c) The urge to move or unpleasant sensations are partially or totally relieved by movement, such as walking or stretching, at least as long as the activity continues; and

(d) The urge to move or unpleasant sensations are worse in the evening or night than during the day or only occur during the evening or night.

**pramipexole hydrochloride monohydrate 250 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9394K NP | 1 | 2 | .. | 28.97 | 30.18 | Sifrol [BY] |

**pramipexole hydrochloride monohydrate 125 microgram tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9393J NP | 1 | 2 | .. | 13.82 | 15.03 | Sifrol [BY] |

## ▪ ROTIGOTINE

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

**rotigotine 6 mg/24 hours patch, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2410W | 1 | 5 | .. | 108.51 | 38.80 | Neupro [UC] |

**rotigotine 4 mg/24 hours patch, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2384L | 1 | 5 | .. | 96.94 | 38.80 | Neupro [UC] |

**rotigotine 8 mg/24 hours patch, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11140H | 1 | 5 | .. | 119.43 | 38.80 | Neupro [UC] |

## ▪ ROTIGOTINE

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

**rotigotine 2 mg/24 hours patch, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2385M | 1 | 5 | .. | 75.48 | 38.80 | Neupro [UC] |

### *Monoamine oxidase B inhibitors*

## ▪ RASAGILINE

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Parkinson disease

**RASAGILINE Tablet 1 mg (as mesilate), 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1952R NP | 1 | 5 | .. | 115.79 | 38.80 | Azilect [TB] |

## ▪ SELEGILINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Late stage Parkinson disease

**Clinical criteria:**

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

**selegiline hydrochloride 5 mg tablet, 100**

| 1973W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 53.13 | 38.80 | Eldepryl [AS] |

*Other dopaminergic agents*

## ▪ ENTACAPONE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination, **AND**
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

**entacapone 200 mg tablet, 100**

| 8367J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 4 | .. | *257.89 | 38.80 | Comtan [NV] |

# ▪ PSYCHOLEPTICS

## ANTIPSYCHOTICS

*Phenothiazines with aliphatic side-chain*

## ▪ CHLORPROMAZINE

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**chlorpromazine hydrochloride 50 mg/2 mL injection, 10 x 2 mL ampoules**

| 1195X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 22.70 | 23.91 | Largactil [SW] |

**chlorpromazine hydrochloride 25 mg tablet, 100**

| 1197B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.28 | 16.49 | Largactil [SW] |

**chlorpromazine hydrochloride 100 mg tablet, 100**

| 1199D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 20.19 | 21.40 | Largactil [SW] |

**chlorpromazine hydrochloride 10 mg tablet, 100**

| 1196Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.77 | 15.98 | Largactil [SW] |

**chlorpromazine hydrochloride 5 mg/mL oral liquid, 100 mL**

| 1201F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 16.35 | 17.56 | Largactil [SW] |

*Phenothiazines with piperazine structure*

## ▪ TRIFLUOPERAZINE

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**trifluoperazine 5 mg tablet, 100**

| 2186C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 25.22 | 26.43 | Stelazine [GH] |

**trifluoperazine 1 mg tablet, 100**

| 2185B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 19.42 | 20.63 | Stelazine [GH] |

**trifluoperazine 2 mg tablet, 100**

| 2386N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 23.50 | 24.71 | Stelazine [GH] |

*Phenothiazines with piperidine structure*

## ▪ PERICYAZINE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**pericyazine 2.5 mg tablet, 100**

| 3052P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.62 | 15.83 | Neulactil [SW] |

**pericyazine 10 mg tablet, 100**

| 3053Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 18.35 | 19.56 | Neulactil [SW] |

*Butyrophenone derivatives*

## ▪ HALOPERIDOL

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**haloperidol 2 mg/mL oral liquid, 100 mL**

| 2763K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 22.68 | 23.89 | Serenace [QA] |

**haloperidol 5 mg/mL injection, 10 x 1 mL ampoules**

| 2768Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 24.20 | 25.41 | Serenace [QA] |

**haloperidol 5 mg tablet, 50**

| 2770T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.61 | 15.82 | Serenace [QA] |

**haloperidol 1.5 mg tablet, 100**

| 2767P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.80 | 16.01 | Serenace [QA] |

**haloperidol 500 microgram tablet, 100**

| 2761H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.51 | 15.72 | Serenace [QA] |

## ▪ HALOPERIDOL DECANOATE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**haloperidol (as decanoate) 50 mg/mL injection, 5 x 1 mL vials**

| 2765M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 30.34 | 31.55 | Haldol decanoate [JC] |

**haloperidol (as decanoate) 150 mg/3 mL injection, 5 x 3 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2766N NP | 1 | .. | .. | 49.67 | 38.80 | Haldol decanoate [JC] |

*Indole derivatives*

## ▪ LURASIDONE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***4246***
Schizophrenia

**lurasidone hydrochloride 80 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10529E NP | 1 | 5 | .. | 144.35 | 38.80 | Latuda [SE] |

**lurasidone hydrochloride 40 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10526B NP | 1 | 5 | .. | 77.72 | 38.80 | Latuda [SE] |

## ▪ ZIPRASIDONE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***4246***
Schizophrenia
**Authority required (STREAMLINED)**
***5742***
Acute mania or mixed episodes
**Clinical criteria:**

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as monotherapy, **AND**
- The treatment must be limited to up to 6 months per episode.

**ziprasidone 80 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9073M NP | 1 | 5 | .. | 189.38 | 38.80 | [a] APO-Ziprasidone [TX] | [a] Zeldox [PF] |

**ziprasidone 40 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9071K NP | 1 | 5 | .. | 100.44 | 38.80 | [a] APO-Ziprasidone [TX] | [a] Zeldox [PF] |

**ziprasidone 20 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9070J NP | 1 | 5 | .. | 55.69 | 38.80 | [a] APO-Ziprasidone [TX] | [a] Zeldox [PF] |

**ziprasidone 60 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9072L NP | 1 | 5 | .. | 144.63 | 38.80 | [a] APO-Ziprasidone [TX] | [a] Zeldox [PF] |

*Thioxanthene derivatives*

## ▪ FLUPENTHIXOL DECANOATE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**flupenthixol decanoate 100 mg/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2257T NP | 1 | .. | .. | 48.44 | 38.80 | Fluanxol Concentrated Depot [LU] |

**flupenthixol decanoate 20 mg/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2255Q NP | 1 | .. | .. | 23.34 | 24.55 | Fluanxol Depot [LU] |

## ▪ ZUCLOPENTHIXOL DECANOATE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**zuclopenthixol decanoate 200 mg/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8097E NP | 1 | .. | .. | 28.28 | 29.49 | Clopixol Depot [LU] |

*Diazepines, oxazepines, thiazepines and oxepines*

## ▪ ASENAPINE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***4246***
Schizophrenia
**Authority required (STREAMLINED)**
***5773***
Acute mania or mixed episodes
**Clinical criteria:**
- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be limited to up to 6 months per episode.

**Authority required (STREAMLINED)**
***5719***
Bipolar I disorder
**Clinical criteria:**
- The treatment must be maintenance therapy, **AND**
- The treatment must be as monotherapy.

**asenapine 10 mg sublingual wafer, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5141N NP | 1 | 5 | .. | 229.26 | 38.80 | Saphris [LU] |

**asenapine 5 mg sublingual wafer, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5140M NP | 1 | 5 | .. | 141.19 | 38.80 | Saphris [LU] |

## ▪ OLANZAPINE

**Caution** Monitor for post-injection syndrome for at least two hours after each injection.
**Note** Special Pricing Arrangements apply.
**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***4304***
Schizophrenia

**olanzapine 210 mg modified release injection [1 vial] (&) inert substance diluent [3 mL vial], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9294E NP | 2 | 5 | .. | *495.77 | 38.80 | Zyprexa Relprevv [LY] |

**olanzapine 300 mg modified release injection [1 vial] (&) inert substance diluent [3 mL vial], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9295F NP | 2 | 5 | .. | *803.77 | 38.80 | Zyprexa Relprevv [LY] |

**olanzapine 405 mg modified release injection [1 vial] (&) inert substance diluent [3 mL vial], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9303P NP | 1 | 5 | .. | 495.77 | 38.80 | Zyprexa Relprevv [LY] |

## ▪ OLANZAPINE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Pharmaceutical benefits that have the form olanzapine tablet 2.5 mg and pharmaceutical benefits that have the form olanzapine tablet 2.5 mg (as benzoate) are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form olanzapine tablet 5 mg and pharmaceutical benefits that have the form olanzapine tablet 5 mg (as benzoate) are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form olanzapine tablet 7.5 mg and pharmaceutical benefits that have the form olanzapine tablet 7.5 mg (as benzoate) are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form olanzapine tablet 10 mg and pharmaceutical benefits that have the form olanzapine tablet 10 mg (as benzoate) are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form olanzapine tablet 5 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 5 mg are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form olanzapine tablet 10 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 10 mg are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form olanzapine tablet 15 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 15 mg are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form olanzapine tablet 20 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 20 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

***5856***

Schizophrenia

**Authority required (STREAMLINED)**

***5869***

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

**olanzapine 20 mg tablet, 28**

| 3385E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 33.24 | 34.45 | [a] APO-Olanzapine ODT [TX]<br>[a] Olanzapine Sandoz ODT 20 [SZ] | [a] Olanzapine AN ODT [EA]<br>[a] Ozin ODT 20 [DO] |

**olanzapine 10 mg tablet, 28**

| 1042W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 22.16 | 23.37 | [a] Olanzapine generichealth 10 [GQ] |

**olanzapine 10 mg tablet, 28**

| 8187X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 22.16 | 23.37 | [a] APO-Olanzapine [TX]<br>[a] Olanzacor 10 [CR]<br>[a] Olanzapine-DRLA [RZ]<br>[a] Olanzapine Sandoz [SZ]<br>[a] Terry White Chemists Olanzapine [TW]<br>[a] Zyprexa [LY] | [a] Chem mart Olanzapine [CH]<br>[a] Olanzapine AN [EA]<br>[a] Olanzapine RBX [RA]<br>[a] Ozin 10 [DO]<br>[a] Zypine [AF] |

**olanzapine 5 mg wafer, 28**

| 8433W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.57 | 17.78 | [a] Zypine ODT [AF] | [a] Zyprexa Zydis [LY] |

**olanzapine 7.5 mg tablet, 28**

| 1041T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 19.40 | 20.61 | [a] Olanzapine generichealth 7.5 [GQ] |

**olanzapine 7.5 mg tablet, 28**

| 8186W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 19.40 | 20.61 | [a] APO-Olanzapine [TX]<br>[a] Olanzacor 7.5 [CR]<br>[a] Olanzapine-DRLA [RZ]<br>[a] Olanzapine Sandoz [SZ]<br>[a] Terry White Chemists Olanzapine [TW]<br>[a] Zyprexa [LY] | [a] Chem mart Olanzapine [CH]<br>[a] Olanzapine AN [EA]<br>[a] Olanzapine RBX [RA]<br>[a] Ozin 7.5 [DO]<br>[a] Zypine [AF] |

**olanzapine 20 mg wafer, 28**

| 8953F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 33.24 | 34.45 | [a] Zypine ODT [AF] | [a] Zyprexa Zydis [LY] |

**olanzapine 15 mg wafer, 28**

| 8952E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 27.70 | 28.91 | [a] Zypine ODT [AF] | [a] Zyprexa Zydis [LY] |

**olanzapine 10 mg wafer, 28**

| 8434X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 22.16 | 23.37 | [a] Zypine ODT [AF] | [a] Zyprexa Zydis [LY] |

**olanzapine 15 mg tablet, 28**

| 3384D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 27.70 | 28.91 | [a] APO-Olanzapine ODT [TX]<br>[a] Olanzapine Sandoz ODT 15 [SZ] | [a] Olanzapine AN ODT [EA]<br>[a] Ozin ODT 15 [DO] |

**olanzapine 5 mg tablet, 28**

| 1037N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.57 | 17.78 | [a] Olanzapine generichealth 5 [GQ] |

**olanzapine 5 mg tablet, 28**

| 8185T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.57 | 17.78 | [a] APO-Olanzapine [TX]<br>[a] Olanzacor 5 [CR]<br>[a] Olanzapine-DRLA [RZ]<br>[a] Olanzapine Sandoz [SZ]<br>[a] Terry White Chemists Olanzapine [TW]<br>[a] Zyprexa [LY] | [a] Chem mart Olanzapine [CH]<br>[a] Olanzapine AN [EA]<br>[a] Olanzapine RBX [RA]<br>[a] Ozin 5 [DO]<br>[a] Zypine [AF] |

**OLANZAPINE Tablet 10 mg (orally disintegrating), 28**

| 3382B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 22.16 | 23.37 | [a] APO-Olanzapine ODT [TX]<br>[a] Olanzapine ODT-DRLA [RZ]<br>[a] Olanzapine Sandoz ODT 10 [SZ] | [a] Olanzapine AN ODT [EA]<br>[a] Olanzapine ODT generichealth 10 [GQ]<br>[a] Ozin ODT 10 [DO] |

**olanzapine 2.5 mg tablet, 28**

| 1024X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 13.86 | 15.07 | [a] Olanzapine generichealth 2.5 [GQ] |

**olanzapine 2.5 mg tablet, 28**

| 8170B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 13.86 | 15.07 | [a] APO-Olanzapine [TX]<br>[a] Olanzacor 2.5 [CR]<br>[a] Olanzapine-DRLA [RZ]<br>[a] Olanzapine Sandoz [SZ]<br>[a] Terry White Chemists Olanzapine [TW]<br>[a] Zyprexa [LY] | [a] Chem mart Olanzapine [CH]<br>[a] Olanzapine AN [EA]<br>[a] Olanzapine RBX [RA]<br>[a] Ozin 2.5 [DO]<br>[a] Zypine [AF] |

**OLANZAPINE Tablet 5 mg (orally disintegrating), 28**

| 3381Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.57 | 17.78 | [a] APO-Olanzapine ODT [TX]<br>[a] Olanzapine ODT-DRLA [RZ]<br>[a] Olanzapine Sandoz ODT 5 [SZ] | [a] Olanzapine AN ODT [EA]<br>[a] Olanzapine ODT generichealth 5 [GQ]<br>[a] Ozin ODT 5 [DO] |

## ▪ QUETIAPINE

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***4246***
Schizophrenia
**Authority required (STREAMLINED)**
***5611***
Acute mania
**Clinical criteria:**

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as monotherapy, **AND**
- The treatment must be limited to up to 6 months per episode.

**Authority required (STREAMLINED)**
***5639***
Bipolar I disorder
**Clinical criteria:**

- The treatment must be maintenance therapy.

### quetiapine 200 mg modified release tablet, 60

| 9203J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 45.07 | 38.80 | [a] APO-Quetiapine XR [TX]<br>[a] Seroquel XR [AP] | [a] QUETIAPINE-AS XR [RW]<br>[a] Tevatiapine XR [TB] |

### quetiapine 50 mg modified release tablet, 60

| 9202H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 22.77 | 23.98 | [a] APO-Quetiapine XR [TX]<br>[a] Seroquel XR [AP] | [a] QUETIAPINE-AS XR [RW]<br>[a] Tevatiapine XR [TB] |

### quetiapine 300 mg modified release tablet, 60

| 9204K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 54.73 | 38.80 | [a] APO-Quetiapine XR [TX]<br>[a] Seroquel XR [AP] | [a] QUETIAPINE-AS XR [RW]<br>[a] Tevatiapine XR [TB] |

### quetiapine 400 mg modified release tablet, 60

| 9205L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 70.58 | 38.80 | [a] APO-Quetiapine XR [TX]<br>[a] Seroquel XR [AP] | [a] QUETIAPINE-AS XR [RW]<br>[a] Tevatiapine XR [TB] |

### quetiapine 150 mg modified release tablet, 60

| 5458G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 27.61 | 28.82 | [a] QUEPINE XR [RW]<br>[a] Tevatiapine XR [TB] | [a] Seroquel XR [AP] |

### quetiapine 200 mg tablet, 60

| 8458E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 33.59 | 34.80 | [a] APO-Quetiapine [TX]<br>[a] Delucon 200 [DO]<br>[a] Pharmacor Quetiapine 200 [CR]<br>[a] Quetiaccord [EF]<br>[a] Quetiapine AN [EA]<br>[a] Quetiapine GH 200 [GQ]<br>[a] Quetiapine Sandoz [SZ]<br>[a] Syquet [AF] | [a] Chem mart Quetiapine [CH]<br>[a] Kaptan [ER]<br>[a] Quetia 200 [RW]<br>[a] Quetiapine Actavis 200 [ED]<br>[a] Quetiapine-DRLA [RZ]<br>[a] Quetiapine RBX [RA]<br>[a] Seroquel [AP]<br>[a] Terry White Chemists Quetiapine [TW] |

### quetiapine 100 mg tablet, 90

| 8457D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 27.61 | 28.82 | [a] APO-Quetiapine [TX]<br>[a] Delucon 100 [DO]<br>[a] Pharmacor Quetiapine 100 [CR]<br>[a] Quetiaccord [EF]<br>[a] Quetiapine AN [EA]<br>[a] Quetiapine GH 100 [GQ]<br>[a] Quetiapine Sandoz [SZ]<br>[a] Syquet [AF] | [a] Chem mart Quetiapine [CH]<br>[a] Kaptan [ER]<br>[a] Quetia 100 [RW]<br>[a] Quetiapine Actavis 100 [ED]<br>[a] Quetiapine-DRLA [RZ]<br>[a] Quetiapine RBX [RA]<br>[a] Seroquel [AP]<br>[a] Terry White Chemists Quetiapine [TW] |

**quetiapine 300 mg tablet, 60**

| 8580N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 44.12 | 38.80 | [a] APO-Quetiapine [TX]<br>[a] Delucon 300 [DO]<br>[a] Pharmacor Quetiapine 300 [CR]<br>[a] Quetiaccord [EF]<br>[a] Quetiapine AN [EA]<br>[a] Quetiapine GH 300 [GQ]<br>[a] Quetiapine Sandoz [SZ]<br>[a] Syquet [AF] | [a] Chem mart Quetiapine [CH]<br>[a] Kaptan [ER]<br>[a] Quetia 300 [RW]<br>[a] Quetiapine Actavis 300 [ED]<br>[a] Quetiapine-DRLA [RZ]<br>[a] Quetiapine RBX [RA]<br>[a] Seroquel [AP]<br>[a] Terry White Chemists Quetiapine [TW] |

## ▪ QUETIAPINE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4391***

Schizophrenia

**Clinical criteria:**

- The treatment must be for dose titration purposes.

**Authority required (STREAMLINED)**

***4396***

Acute mania

**Clinical criteria:**

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as monotherapy, **AND**
- The treatment must be for dose titration purposes.

**Authority required (STREAMLINED)**

***4385***

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy, **AND**
- The treatment must be for dose titration purposes.

**quetiapine 25 mg tablet, 60**

| 8456C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 16.93 | 18.14 | [a] APO-Quetiapine [TX]<br>[a] Delucon 25 [DO]<br>[a] Pharmacor Quetiapine 25 [CR]<br>[a] Quetiaccord [EF]<br>[a] Quetiapine AN [EA]<br>[a] Quetiapine GH 25 [GQ]<br>[a] Quetiapine Sandoz [SZ]<br>[a] Syquet [AF] | [a] Chem mart Quetiapine [CH]<br>[a] Kaptan [ER]<br>[a] Quetia 25 [RW]<br>[a] Quetiapine Actavis 25 [ED]<br>[a] Quetiapine-DRLA [RZ]<br>[a] Quetiapine RBX [RA]<br>[a] Seroquel [AP]<br>[a] Terry White Chemists Quetiapine [TW] |

*Benzamides*

## ▪ AMISULPRIDE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4246***

Schizophrenia

**amisulpride 400 mg tablet, 60**

| 8596K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 65.46 | 38.80 | [a] Amipride 400 [RW]<br>[a] Amisulpride AN [EA]<br>[a] APO-Amisulpride [TX]<br>[a] Sulprix [AF] | [a] Amisulpride 400 Winthrop [WA]<br>[a] Amisulpride Sandoz [SZ]<br>[a] Solian 400 [SW] |

**amisulpride 100 mg tablet, 30**

| 8594H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 18.05 | 19.26 | [a] Amisulpride 100 Winthrop [WA]<br>[a] Amisulpride Sandoz [SZ]<br>[a] Solian 100 [SW] | [a] Amisulpride AN [EA]<br>[a] APO-Amisulpride [TX]<br>[a] Sulprix [AF] |

**amisulpride 100 mg/mL oral liquid, 60 mL**

| 8736T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *140.47 | 38.80 | Solian Solution [SW] |

**amisulpride 200 mg tablet, 60**

| 8595J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 41.08 | 38.80 | [a] Amisulpride 200 Winthrop [WA]<br>[a] Amisulpride Sandoz [SZ]<br>[a] Solian 200 [SW] | [a] Amisulpride AN [EA]<br>[a] APO-Amisulpride [TX]<br>[a] Sulprix [AF] |

*Other antipsychotics*

## ▪ ARIPIPRAZOLE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***4246***
Schizophrenia

**aripiprazole 400 mg injection: modified release [1 x 400 mg vial] (&) inert substance diluent [1 vial], 1 pack**

| 10219W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 373.70 | 38.80 | Abilify Maintena [LU] |

**aripiprazole 15 mg tablet, 30**

| 8718W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 161.22 | 38.80 | [a] Abilify [OS]<br>[a] APO-Aripiprazole [TX]<br>[a] Aripiprazole GH [GQ]<br>[a] Tevaripiprazole [TB] | [a] Abyraz [AF]<br>[a] Aripiprazole AN [EA]<br>[a] Aripiprazole Sandoz [SZ] |

**aripiprazole 30 mg tablet, 30**

| 8720Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 235.28 | 38.80 | [a] Abilify [OS]<br>[a] APO-Aripiprazole [TX]<br>[a] Aripiprazole GH [GQ]<br>[a] Tevaripiprazole [TB] | [a] Abyraz [AF]<br>[a] Aripiprazole AN [EA]<br>[a] Aripiprazole Sandoz [SZ] |

**aripiprazole 20 mg tablet, 30**

| 8719X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 193.94 | 38.80 | [a] Abilify [OS]<br>[a] APO-Aripiprazole [TX]<br>[a] Aripiprazole GH [GQ]<br>[a] Tevaripiprazole [TB] | [a] Abyraz [AF]<br>[a] Aripiprazole AN [EA]<br>[a] Aripiprazole Sandoz [SZ] |

**aripiprazole 10 mg tablet, 30**

| 8717T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 116.89 | 38.80 | [a] Abilify [OS]<br>[a] APO-Aripiprazole [TX]<br>[a] Aripiprazole GH [GQ]<br>[a] Tevaripiprazole [TB] | [a] Abyraz [AF]<br>[a] Aripiprazole AN [EA]<br>[a] Aripiprazole Sandoz [SZ] |

**aripiprazole 300 mg injection: modified release [1 x 300 mg vial] (&) inert substance diluent [1 vial], 1 pack**

| 10224D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 299.91 | 38.80 | Abilify Maintena [LU] |

## ▪ BREXPIPRAZOLE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4246***

Schizophrenia

**brexpiprazole 2 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11188W NP | 1 | 5 | .. | 142.37 | 38.80 | Rexulti [LU] |

**brexpiprazole 4 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11184P NP | 1 | 5 | .. | 142.37 | 38.80 | Rexulti [LU] |

**brexpiprazole 3 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11190Y NP | 1 | 5 | .. | 142.37 | 38.80 | Rexulti [LU] |

**brexpiprazole 1 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11189X NP | 1 | .. | .. | 142.37 | 38.80 | Rexulti [LU] |

## ▪ PALIPERIDONE

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4246***

Schizophrenia

**paliperidone 3 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9140C NP | 1 | 5 | .. | 74.29 | 38.80 | Invega [JC] |

**paliperidone 25 mg modified release injection, 1 syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5100K NP | 1 | 5 | .. | 134.77 | 38.80 | Invega Sustenna [JC] |

**paliperidone 150 mg modified release injection, 1 syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5109X NP | 1 | 5 | .. | 414.09 | 38.80 | Invega Sustenna [JC] |

**paliperidone 9 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9142E NP | 1 | 5 | .. | 203.00 | 38.80 | Invega [JC] |

**paliperidone 75 mg modified release injection, 1 syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5103N NP | 1 | 5 | .. | 337.84 | 38.80 | Invega Sustenna [JC] |

**paliperidone 50 mg modified release injection, 1 syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5102M NP | 1 | 5 | .. | 260.81 | 38.80 | Invega Sustenna [JC] |

**paliperidone 100 mg modified release injection, 1 syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5107T NP | 1 | 5 | .. | 414.09 | 38.80 | Invega Sustenna [JC] |

**paliperidone 6 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9141D NP | 1 | 5 | .. | 138.77 | 38.80 | Invega [JC] |

## ▪ PALIPERIDONE

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Patient dosage is to be determined as per the dose transition table in the Product Information based on the maintenance dose of paliperidone once monthly injection.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority required (STREAMLINED)**

***6832***

Schizophrenia

**Clinical criteria:**

- Patient must have previously received and be stabilised on PBS-subsidised paliperidone once-monthly injection for at least 4 consecutive months.

**paliperidone 263 mg/1.315 mL modified release injection, 1.315 mL syringe**

| 11072R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 1003.94 | 38.80 | Invega Trinza [JC] |

**paliperidone 350 mg/1.75 mL modified release injection, 1.75 mL syringe**

| 11094X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 1219.20 | 38.80 | Invega Trinza [JC] |

**paliperidone 525 mg/2.625 mL modified release injection, 2.625 mL syringe**

| 11066K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 1219.20 | 38.80 | Invega Trinza [JC] |

**paliperidone 175 mg/0.875 mL modified release injection, 0.875 mL syringe**

| 11085K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 772.84 | 38.80 | Invega Trinza [JC] |

## ▪ RISPERIDONE

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4246***

Schizophrenia

**Authority required (STREAMLINED)**

***5907***

Acute mania

**Clinical criteria:**

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as adjunctive therapy to mood stabilisers, **AND**
- The treatment must be limited to up to 6 months per episode.

**risperidone 1 mg/mL oral liquid, 100 mL**

| 8100H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 112.55 | 38.80 | Risperdal [JC] |

**risperidone 3 mg tablet, 60**

| 3171X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 33.09 | 34.30 | [a] APO-Risperidone [TX]<br>[a] Rispa [RW]<br>[a] Risperidone AMNEAL [EF]<br>[a] Risperidone generichealth [GQ]<br>[a] Rispernia [ER] | [a] Ozidal [RA]<br>[a] Risperdal [JC]<br>[a] Risperidone AN [EA]<br>[a] Risperidone Sandoz [SZ]<br>[a] Rixadone [AF] |

**risperidone 2 mg tablet, 60**

| 3170W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 25.36 | 26.57 | [a] APO-Risperidone [TX]<br>[a] Rispa [RW]<br>[a] Rispericor 2 [CR]<br>[a] Risperidone AN [EA]<br>[a] Risperidone Sandoz [SZ]<br>[a] Rixadone [AF] | [a] Ozidal [RA]<br>[a] Risperdal [JC]<br>[a] Risperidone AMNEAL [EF]<br>[a] Risperidone generichealth [GQ]<br>[a] Rispernia [ER] |

**risperidone 4 mg tablet, 60**

| 3172Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 40.79 | 38.80 | [a] APO-Risperidone [TX]<br>[a] Rispa [RW]<br>[a] Risperidone AMNEAL [EF]<br>[a] Risperidone generichealth [GQ]<br>[a] Rispernia [ER] | [a] Ozidal [RA]<br>[a] Risperdal [JC]<br>[a] Risperidone AN [EA]<br>[a] Risperidone Sandoz [SZ]<br>[a] Rixadone [AF] |

**risperidone 1 mg tablet, 60**

| 3169T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.33 | 18.54 | [a] APO-Risperidone [TX]<br>[a] Rispa [RW]<br>[a] Rispericor 1 [CR]<br>[a] Risperidone AN [EA]<br>[a] Risperidone Sandoz [SZ]<br>[a] Rixadone [AF] | [a] Ozidal [RA]<br>[a] Risperdal [JC]<br>[a] Risperidone AMNEAL [EF]<br>[a] Risperidone generichealth [GQ]<br>[a] Rispernia [ER] |

## ▪ RISPERIDONE

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***6897***

Severe behavioural disturbances

**Clinical criteria:**

- Patient must have autism spectrum disorder, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

- Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**Authority required (STREAMLINED)**

***6938***

Severe behavioural disturbances

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have autism spectrum disorder, **AND**
- Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

- Patient must be aged 18 years or older.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**risperidone 2 mg tablet, 60**

| 9079W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 25.36 | 26.57 | [a] APO-Risperidone [TX]<br>[a] Rispa [RW]<br>[a] Rispericor 2 [CR]<br>[a] Risperidone AN [EA]<br>[a] Risperidone Sandoz [SZ]<br>[a] Rixadone [AF] | [a] Ozidal [RA]<br>[a] Risperdal [JC]<br>[a] Risperidone AMNEAL [EF]<br>[a] Risperidone generichealth [GQ]<br>[a] Rispernia [ER] |

## ▪ RISPERIDONE

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***4246***
Schizophrenia
**Authority required (STREAMLINED)**
***5912***
Bipolar I disorder
**Clinical criteria:**

- The condition must be refractory to treatment, **AND**
- The treatment must be in combination with lithium or sodium valproate, **AND**
- The treatment must be maintenance therapy.

**risperidone 37.5 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

8781E (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *345.33 | 38.80 | Risperdal Consta [JC] |

**risperidone 50 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

8782F (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *423.51 | 38.80 | Risperdal Consta [JC] |

**risperidone 25 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

8780D (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *266.31 | 38.80 | Risperdal Consta [JC] |

## ▪ RISPERIDONE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** For item codes 8869T and 1846E, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**
***5903***
Schizophrenia

**risperidone 500 microgram tablet, 60**

8869T (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 18.22 | 19.43 | [a] Ozidal [RA] | [a] Rispa [RW] |
| | | | | | [a] Rispericor 0.5 [CR] | [a] Risperidone AMNEAL [EF] |
| | | | | | [a] Risperidone AN [EA] | [a] Risperidone Sandoz [SZ] |
| | | | | | [a] Rispernia [ER] | [a] Rixadone [AF] |

**risperidone 500 microgram tablet, 20**

1846E (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 5 | .. | *18.22 | 19.43 | [a] APO-Risperidone [TX] | [a] Risperdal [JC] |

## ▪ RISPERIDONE

**Caution** In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalaties) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***5993***
Behavioural disturbances
**Clinical criteria:**

- The condition must be characterised by psychotic symptoms and aggression, **AND**
- Patient must have dementia of the Alzheimer type, **AND**
- Patient must have failed to respond to non-pharmacological methods of treatment, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**Authority required (STREAMLINED)**
***6897***
Severe behavioural disturbances
**Clinical criteria:**

- Patient must have autism spectrum disorder, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**

- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

- Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**Authority required (STREAMLINED)**

***6938***

Severe behavioural disturbances

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have autism spectrum disorder, **AND**
- Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

- Patient must be aged 18 years or older.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**risperidone 1 mg/mL oral liquid, 100 mL**

9293D (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 112.55 | 38.80 | Risperdal [JC] |

**risperidone 1 mg tablet, 60**

8789N (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 17.33 | 18.54 | [a] APO-Risperidone [TX] | [a] Ozidal [RA] |
| | | | | | [a] Rispa [RW] | [a] Risperdal [JC] |
| | | | | | [a] Rispericor 1 [CR] | [a] Risperidone AMNEAL [EF] |
| | | | | | [a] Risperidone AN [EA] | [a] Risperidone generichealth [GQ] |
| | | | | | [a] Risperidone Sandoz [SZ] | [a] Rispernia [ER] |
| | | | | | [a] Rixadone [AF] | |

## ▪ RISPERIDONE

**Caution** In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalaties) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** For items 8787L and 1842Y, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

***6010***

Behavioural disturbances

**Clinical criteria:**

- The condition must be characterised by psychotic symptoms and aggression, **AND**
- Patient must have dementia of the Alzheimer type, **AND**
- Patient must have failed to respond to non-pharmacological methods of treatment, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**Authority required (STREAMLINED)**

***6898***

Severe behavioural disturbances

**Clinical criteria:**

- Patient must have autism spectrum disorder, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

- Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**Authority required (STREAMLINED)**

***6899***

Severe behavioural disturbances

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have autism spectrum disorder, **AND**
- Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

- Patient must be aged 18 years or older.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**risperidone 500 microgram tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8787L NP | 1 | 2 | .. | 18.22 | 19.43 | [a] Ozidal [RA]<br>[a] Rispericor 0.5 [CR]<br>[a] Risperidone AN [EA]<br>[a] Rispernia [ER] | [a] Rispa [RW]<br>[a] Risperidone AMNEAL [EF]<br>[a] Risperidone Sandoz [SZ]<br>[a] Rixadone [AF] |

**risperidone 500 microgram tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1842Y NP | 3 | 2 | .. | *18.22 | 19.43 | [a] APO-Risperidone [TX] | [a] Risperdal [JC] |

## ANXIOLYTICS

*Benzodiazepine derivatives*

### ▪ ALPRAZOLAM

**Note** The panic disorder must not be attributable to some known organic factor.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Panic disorder

**Clinical criteria:**

- The treatment must be for use when other treatments have failed; OR
- The treatment must be for use when other treatments are inappropriate.

**alprazolam 250 microgram tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2130D NP | 0.2 | .. | .. | *17.40 | 18.61 | [a] Alprax 0.25 [QA] | [a] Kalma 0.25 [AF] |

### ▪ ALPRAZOLAM

**Note** Pharmaceutical benefits that have the form alprazolam tablet 1 mg are equivalent for the purposes of substitution.

**Note** The panic disorder must not be attributable to some known organic factor.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Panic disorder

**Clinical criteria:**

- The treatment must be for use when other treatments have failed; OR
- The treatment must be for use when other treatments are inappropriate.

**alprazolam 1 mg tablet, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11186R NP | 1 | .. | .. | 17.80 | 19.01 | [a] Alprax 1 [QA] |

**alprazolam 1 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2132F NP | 0.2 | .. | .. | *22.79 | 24.00 | [a] Alprax 1 [QA] | [a] Kalma 1 [AF] |

### ▪ ALPRAZOLAM

**Note** Pharmaceutical benefits that have the form alprazolam tablet 500 micrograms are equivalent for the purposes of substitution.

**Note** The panic disorder must not be attributable to some known organic factor.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Panic disorder

**Clinical criteria:**

- The treatment must be for use when other treatments have failed; OR
- The treatment must be for use when other treatments are inappropriate.

**alprazolam 500 microgram tablet, 10**

| 11187T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 16.74 | 17.95 | [a] Alprax 0.5 [QA] |

**alprazolam 500 microgram tablet, 50**

| 2131E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 0.2 | .. | .. | *21.10 | 22.31 | [a] Alprax 0.5 [QA] | [a] Kalma 0.5 [AF] |

## ▪ DIAZEPAM

**diazepam 2 mg tablet, 50**

| 5071X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 12.41 | 13.62 | [a] Antenex 2 [AF]<br>[a] Valpam 2 [RW] | [a] APO-Diazepam [TX] |

**diazepam 5 mg tablet, 50**

| 5072Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 12.48 | 13.69 | [a] Antenex 5 [AF]<br>[a] Ranzepam [RA] | [a] APO-Diazepam [TX]<br>[a] Valpam 5 [RW] |
| | | | [B]2.19 | 14.67 | 13.69 | [a] Valium [RO] | |

**diazepam 10 mg/2 mL injection, 5 x 2 mL ampoules**

| 5073B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 17.11 | 18.32 | Hospira Pty Limited [PF] |

## ▪ DIAZEPAM

**Authority required**

Chronic spasticity

**Population criteria:**

- Patient must be under 18 years of age.

**diazepam 1 mg/mL oral liquid, 100 mL**

| 2669L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | .. | .. | 42.95 | 38.80 | Diazepam Elixir [ON] |

## ▪ DIAZEPAM

**Note** Authorities for increased maximum quantities and/or repeats for the oral forms of diazepam will be granted only for
(i) the treatment of disabling spasticity; or
(ii) malignant neoplasia (late stage); or
(iii) use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal; or
(iv) use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.
Up to six months' treatment (i.e. one month's treatment with five repeats) may be requested.

**diazepam 2 mg tablet, 50**

| 3161J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 12.41 | 13.62 | [a] Antenex 2 [AF]<br>[a] Valpam 2 [RW] | [a] APO-Diazepam [TX] |

**diazepam 5 mg tablet, 50**

| 3162K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 12.48 | 13.69 | [a] Antenex 5 [AF]<br>[a] Ranzepam [RA] | [a] APO-Diazepam [TX]<br>[a] Valpam 5 [RW] |
| | | | [B]2.19 | 14.67 | 13.69 | [a] Valium [RO] | |

## ▪ DIAZEPAM

**Note** Authorities for increased maximum quantities and/or repeats for the oral forms of diazepam will be granted only for
(i) the treatment of disabling spasticity; or
(ii) malignant neoplasia (late stage); or
(iii) use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past six months, to be benzodiazepine

dependent by an unsuccessful attempt at gradual withdrawal; or
(iv) use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.

**Note** Up to six months' treatment (i.e. one month's treatment with five repeats) may be requested.

**diazepam 10 mg/2 mL injection, 5 x 2 mL ampoules**

| 2558P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 17.11 | 18.32 | Hospira Pty Limited [PF] |

## ▪ OXAZEPAM

**oxazepam 30 mg tablet, 25**

| 5193H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 12.17 | 13.38 | [a] Alepam 30 [AF]<br>[a] Murelax [RW] | [a] APO-Oxazepam [TX] |
| | | | [B]2.33 | 14.50 | 13.38 | [a] Serepax [QA] | |

**oxazepam 15 mg tablet, 25**

| 5192G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 12.51 | 13.72 | [a] Alepam 15 [AF] |
| | | | [B]2.66 | 15.17 | 13.72 | [a] Serepax [QA] |

## ▪ OXAZEPAM

**Note** Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of oxazepam below.

**oxazepam 30 mg tablet, 25**

| 3133X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 12.17 | 13.38 | [a] Alepam 30 [AF]<br>[a] Murelax [RW] | [a] APO-Oxazepam [TX] |
| | | | [B]2.33 | 14.50 | 13.38 | [a] Serepax [QA] | |

**oxazepam 15 mg tablet, 25**

| 3132W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 12.51 | 13.72 | [a] Alepam 15 [AF] |
| | | | [B]2.66 | 15.17 | 13.72 | [a] Serepax [QA] |

## ▪ OXAZEPAM

**Authority required**
Malignant neoplasia (late stage)
**Authority required**
Anxiety
**Clinical criteria:**

- Patient must be receiving this drug for the management of anxiety, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority required**
Anxiety
**Clinical criteria:**

- Patient must be receiving this drug for the management of anxiety, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**oxazepam 30 mg tablet, 25**

| 3135B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *13.25 | 14.46 | [a] Alepam 30 [AF]<br>[a] Murelax [RW] | [a] APO-Oxazepam [TX] |
| | | | [B]4.66 | *17.91 | 14.46 | [a] Serepax [QA] | |

**oxazepam 15 mg tablet, 25**

| 3134Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *13.93 | 15.14 | [a] Alepam 15 [AF] |
| | | | [B]5.32 | *19.25 | 15.14 | [a] Serepax [QA] |

## HYPNOTICS AND SEDATIVES

*Benzodiazepine derivatives*

### ▪ NITRAZEPAM

**nitrazepam 5 mg tablet, 25**

5189D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 12.70 | 13.91 | [a] Alodorm [AF] |
| | | [B]1.24 | 13.94 | 13.91 | [a] Mogadon [IA] |

DP

### ▪ NITRAZEPAM

**Note** Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of nitrazepam below.

**nitrazepam 5 mg tablet, 25**

2723H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 12.70 | 13.91 | [a] Alodorm [AF] |
| | | [B]1.24 | 13.94 | 13.91 | [a] Mogadon [IA] |

NP

### ▪ NITRAZEPAM

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Myoclonic epilepsy

**Authority required**

Malignant neoplasia (late stage)

**Authority required**

Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority required**

Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**nitrazepam 5 mg tablet, 25**

2732T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *14.31 | 15.52 | [a] Alodorm [AF] |
| | | [B]2.48 | *16.79 | 15.52 | [a] Mogadon [IA] |

NP

### ▪ TEMAZEPAM

**temazepam 10 mg tablet, 25**

5221T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 12.17 | 13.38 | [a] APO-Temazepam [TX]<br>[a] Temtabs [FM] | [a] Temaze [AF] |
| | | [B]3.48 | 15.65 | 13.38 | [a] Normison [QA] | |

DP

### ▪ TEMAZEPAM

**Note** Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of temazepam.

**temazepam 10 mg tablet, 25**

2089Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 12.17 | 13.38 | [a] APO-Temazepam [TX]<br>[a] Temtabs [FM] | [a] Temaze [AF] |
| | | [B]3.48 | 15.65 | 13.38 | [a] Normison [QA] | |

NP

## ▪ TEMAZEPAM

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Malignant neoplasia (late stage)

**Authority required**

Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority required**

Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**temazepam 10 mg tablet, 25**

| 2088X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *13.25 | 14.46 | [a] APO-Temazepam [TX]<br>[a] Temtabs [FM] | [a] Temaze [AF] |
| | | | [B]6.96 | *20.21 | 14.46 | [a] Normison [QA] | |

# ▪ PSYCHOANALEPTICS

## ANTIDEPRESSANTS

*Non-selective monoamine reuptake inhibitors*

## ▪ AMITRIPTYLINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**amitriptyline hydrochloride 25 mg tablet, 50**

| 2418G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 13.79 | 15.00 | [a] Amitriptyline Alphapharm 25 [AL]<br>[a] Chem mart Amitriptyline [CH]<br>[a] Terry White Chemists Amitriptyline [TW] | [a] APO-Amitriptyline 25 [TX]<br>[a] ENTRIP [RW] |
| | | | [B]1.96 | 15.75 | 15.00 | [a] Endep 25 [AF] | |

**amitriptyline hydrochloride 50 mg tablet, 50**

| 2429W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 14.19 | 15.40 | [a] Amitriptyline Alphapharm 50 [AL]<br>[a] Chem mart Amitriptyline [CH]<br>[a] Terry White Chemists Amitriptyline [TW] | [a] APO-Amitriptyline 50 [TX]<br>[a] ENTRIP [RW] |
| | | | [B]1.95 | 16.14 | 15.40 | [a] Endep 50 [AF] | |

**amitriptyline hydrochloride 10 mg tablet, 50**

| 2417F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 13.60 | 14.81 | [a] Amitriptyline Alphapharm 10 [AL]<br>[a] Chem mart Amitriptyline [CH]<br>[a] Terry White Chemists Amitriptyline [TW] | [a] APO-Amitriptyline 10 [TX]<br>[a] ENTRIP [RW] |
| | | | [B]1.95 | 15.55 | 14.81 | [a] Endep 10 [AF] | |

## ▪ CLOMIPRAMINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Cataplexy

**Clinical criteria:**

- The condition must be associated with narcolepsy.

**Restricted benefit**

Obsessive-compulsive disorder

**Restricted benefit**

Phobic disorders

**Population criteria:**

- Patient must be an adult.

### clomipramine hydrochloride 25 mg tablet, 50

1561E (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 17.03 | 18.24 | [a] GenRx Clomipramine [GX] | [a] Placil [AF] |
| | | [B]4.41 | 21.44 | 18.24 | [a] Anafranil 25 [SZ] | |

## ▪ DOTHIEPIN

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### dothiepin hydrochloride 75 mg tablet, 30

1358L (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 13.66 | 14.87 | Dothep 75 [AF] |

### dothiepin hydrochloride 25 mg capsule, 50

1357K (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 13.66 | 14.87 | Dothep 25 [AF] |

## ▪ DOXEPIN

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### doxepin 50 mg tablet, 50

1012G (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 14.89 | 16.10 | Deptran 50 [AF] |

### doxepin 10 mg capsule, 50

1011F (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 13.98 | 15.19 | Deptran 10 [AF] |
| | | [B]7.00 | 20.98 | 15.19 | Sinequan [PF] |

### doxepin 25 mg capsule, 50

1013H (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 14.09 | 15.30 | Deptran 25 [AF] |
| | | [B]7.00 | 21.09 | 15.30 | Sinequan [PF] |

## ▪ IMIPRAMINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### imipramine hydrochloride 10 mg tablet, 50

2420J (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 15.36 | 16.57 | Tofranil 10 [GH] |

**imipramine hydrochloride 25 mg tablet, 50**

| 2421K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 18.73 | 19.94 | Tofranil 25 [GH] |

## ▪ NORTRIPTYLINE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
Major depression
**Clinical criteria:**
- The treatment must be for use when other anti-depressant therapy has failed.

**Restricted benefit**
Major depression
**Clinical criteria:**
- The treatment must be for use when other anti-depressant therapy is contraindicated.

**nortriptyline 25 mg tablet, 50**

| 2523T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 17.11 | 18.32 | [a] Allegron [RW] | [a] NortriTABS 25 mg [GH] |

**nortriptyline 10 mg tablet, 50**

| 2522R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 15.87 | 17.08 | [a] Allegron [RW] | [a] NortriTABS 10 mg [GH] |

*Selective serotonin reuptake inhibitors*

## ▪ CITALOPRAM

**Restricted benefit**
Major depressive disorders

**citalopram 10 mg tablet, 28**

| 8702B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 12.06 | 13.27 | [a] Celapram [AF]<br>[a] Citalopram AN [EF] | [a] Citalopram Actavis [EA]<br>[a] Talam [RW] |

**citalopram 40 mg tablet, 28**

| 8703C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 13.28 | 14.49 | [a] APO-Citalopram [TX]<br>[a] Celapram [AF]<br>[a] Citalopram AN [EA]<br>[a] Talam [RW] | [a] Auro-Citalopram 40 [DO]<br>[a] Citalopram Actavis [ED]<br>[a] Citalopram Sandoz [SZ] |

**citalopram 20 mg tablet, 28**

| 8220P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 12.39 | 13.60 | [a] APO-Citalopram [TX]<br>[a] Celapram [AF]<br>[a] Chem mart Citalopram [CH]<br>[a] Citalopram AN [EA]<br>[a] Pharmacor Citalo 20 [CR]<br>[a] Terry White Chemists Citalopram [TW] | [a] Auro-Citalopram 20 [DO]<br>[a] Celica [RA]<br>[a] Citalopram Actavis [ED]<br>[a] Citalopram Sandoz [SZ]<br>[a] Talam [RW] |
| | | | [B]6.50 | 18.89 | 13.60 | [a] Cipramil [LU] | |

## ▪ ESCITALOPRAM

**Restricted benefit**
Major depressive disorders

**escitalopram 10 mg tablet, 28**

| 8700X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 13.19 | 14.40 | [a] APO-Escitalopram [TX]<br>[a] Chem mart Escitalopram [CH]<br>[a] Escicor 10 [RA]<br>[a] Escitalopram-DRLA [RZ]<br>[a] Esipram [CF]<br>[a] Lexam 10 [RW] | [a] Blooms the Chemist Escitalopram [IB]<br>[a] Cilopam-S [ER]<br>[a] Escitalopram AN [EA]<br>[a] Escitalopram generichealth [GQ]<br>[a] Esitalo [SZ]<br>[a] LoxaLate [AF] |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | [a] Pharmacor Escitalopram 10 [CR] | [a] Terry White Chemists Escitalopram [TW] |
| | | [B]8.49 | 21.68 | 14.40 | [a] Lexapro [LU] | |

**escitalopram 20 mg tablet, 28**

8701Y

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 13.21 | 14.42 | [a] APO-Escitalopram [TX] | [a] Blooms the Chemist Escitalopram [IB] |
| | | | | | [a] Chem mart Escitalopram [CH] | [a] Cilopam-S [ER] |
| | | | | | [a] Escicor 20 [RA] | [a] Escitalopram AN [EA] |
| | | | | | [a] Escitalopram-DRLA [RZ] | [a] Escitalopram generichealth [GQ] |
| | | | | | [a] Esipram [CF] | [a] Esitalo [SZ] |
| | | | | | [a] Lexam 20 [RW] | [a] LoxaLate [AF] |
| | | | | | [a] Pharmacor Escitalopram 20 [CR] | [a] Terry White Chemists Escitalopram [TW] |
| | | [B]8.84 | 22.05 | 14.42 | [a] Lexapro [LU] | |

## ▪ ESCITALOPRAM

**Restricted benefit**

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**Restricted benefit**

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**escitalopram 10 mg tablet, 28**

9432K

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 13.19 | 14.40 | [a] Esipram [CF] |
| | | [B]8.49 | 21.68 | 14.40 | [a] Lexapro [LU] |

**escitalopram 20 mg tablet, 28**

9433L

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 13.21 | 14.42 | [a] Esipram [CF] |
| | | [B]8.84 | 22.05 | 14.42 | [a] Lexapro [LU] |

## ▪ ESCITALOPRAM

**Restricted benefit**

Major depressive disorders

**Restricted benefit**

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**

- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**Restricted benefit**

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**escitalopram 20 mg/mL oral liquid, 15 mL**

10181W (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 37.06 | 38.27 | Lexapro [LU] |

## ▪ FLUOXETINE

**Restricted benefit**

Major depressive disorders

**Restricted benefit**

Obsessive-compulsive disorder

**fluoxetine 20 mg dispersible tablet, 28**

8270G (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 14.80 | 16.01 | [a] Lovan 20 Tab [AL] | [a] Zactin Tablet [AF] |
| | | [B]1.18 | 15.98 | 16.01 | [a] Prozac Tab [LY] | |

**fluoxetine 20 mg capsule, 28**

1434L (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 14.80 | 16.01 | [a] APO-Fluoxetine [TX] | [a] Auscap Aspen [RW] |
| | | | | | [a] Blooms the Chemist Fluoxetine [IB] | [a] Chem mart Fluoxetine [CH] |
| | | | | | [a] FLUOTEX [RF] | [a] Fluoxetine AN [EA] |
| | | | | | [a] Fluoxetine-GA [ED] | [a] Fluoxetine generichealth [GQ] |
| | | | | | [a] Fluoxetine Sandoz [SZ] | [a] GenRx Fluoxetine [GX] |
| | | | | | [a] Lovan [AL] | [a] Terry White Chemists Fluoxetine [TW] |
| | | | | | [a] Zactin [AF] | |
| | | [B]1.18 | 15.98 | 16.01 | [a] Prozac 20 [LY] | |

## ▪ FLUVOXAMINE

**Restricted benefit**

Major depressive disorders

**Restricted benefit**

Obsessive-compulsive disorder

**fluvoxamine maleate 100 mg tablet, 30**

8174F (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 19.66 | 20.87 | [a] APO-Fluvoxamine [TX] | [a] Faverin 100 [RW] |
| | | | | | [a] Fluvoxamine AN [ED] | [a] Fluvoxamine GA [EA] |
| | | | | | [a] Movox 100 [AF] | [a] Voxam [SZ] |
| | | [B]3.07 | 22.73 | 20.87 | [a] Luvox [GO] | |

**fluvoxamine maleate 50 mg tablet, 30**

| 8512B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.75 | 17.96 | [a] APO-Fluvoxamine [TX]<br>[a] Fluvoxamine AN [ED]<br>[a] Movox 50 [AL] | [a] Faverin 50 [RW]<br>[a] Fluvoxamine GA [EA]<br>[a] Voxam [SZ] |
| | | | [B]3.08 | 19.83 | 17.96 | [a] Luvox [GO] | |

## ▪ PAROXETINE

**Restricted benefit**

Major depressive disorders

**Restricted benefit**

Obsessive-compulsive disorder

**Restricted benefit**

Panic disorder

**paroxetine 20 mg tablet, 30**

| 2242B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.51 | 15.72 | [a] APO-Paroxetine [TX]<br>[a] Extine 20 [RW]<br>[a] Paroxetine AN [EA]<br>[a] Paroxetine Sandoz [SZ]<br>[a] Roxet 20 [DO] | [a] Chem mart Paroxetine [CH]<br>[a] GenRx Paroxetine [GX]<br>[a] Paroxetine GH [GQ]<br>[a] Paxtine [AF]<br>[a] Terry White Chemists Paroxetine [TW] |
| | | | [B]2.58 | 17.09 | 15.72 | [a] Aropax [AS] | |

## ▪ SERTRALINE

**Restricted benefit**

Major depressive disorders

**sertraline 100 mg tablet, 30**

| 2237R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 12.78 | 13.99 | [a] APO-Sertraline [TX]<br>[a] Chem mart Sertraline [CH]<br>[a] Sertra 100 [RW]<br>[a] Sertraline AN [EA]<br>[a] Sertraline Sandoz [SZ]<br>[a] Terry White Chemists Sertraline [TW] | [a] Auro-Sertraline 100 [DO]<br>[a] Eleva 100 [AF]<br>[a] Sertracor 100 [CR]<br>[a] Sertraline generichealth [GQ]<br>[a] Setrona [RA] |
| | | | [B]5.80 | 18.58 | 13.99 | [a] Zoloft [PF] | |

**sertraline 50 mg tablet, 30**

| 2236Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 12.78 | 13.99 | [a] APO-Sertraline [TX]<br>[a] Chem mart Sertraline [CH]<br>[a] Sertra 50 [RW]<br>[a] Sertraline AN [EA]<br>[a] Sertraline Sandoz [SZ]<br>[a] Terry White Chemists Sertraline [TW] | [a] Auro-Sertraline 50 [DO]<br>[a] Eleva 50 [AF]<br>[a] Sertracor 50 [CR]<br>[a] Sertraline generichealth [GQ]<br>[a] Setrona [RA] |
| | | | [B]5.80 | 18.58 | 13.99 | [a] Zoloft [PF] | |

## ▪ SERTRALINE

**Restricted benefit**

Obsessive-compulsive disorder

**Restricted benefit**

Panic disorder

**Clinical criteria:**

- The treatment must be for use when other treatments have failed; OR
- The treatment must be for use when other treatments are inappropriate.

**sertraline 100 mg tablet, 30**

| 8837D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 12.78 | 13.99 | [a] Auro-Sertraline 100 [DO]<br>[a] Sertraline AN [EA] | [a] Eleva 100 [AF] |
| | | | [B]5.80 | 18.58 | 13.99 | [a] Zoloft [PF] | |

**sertraline 50 mg tablet, 30**

| 8836C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 12.78 | 13.99 | [a] Auro-Sertraline 50 [DO] | [a] Eleva 50 [AF] |

| | | | | |
|---|---|---|---|---|
| | | | | [a] Sertraline AN [EA] |
| [B]5.80 | 18.58 | 13.99 | [a] Zoloft [PF] | |

*Monoamine oxidase inhibitors, non-selective*

## ▪ PHENELZINE

**Caution** This drug is an irreversible monoamine oxidase inhibitor.

**Restricted benefit**

Depression

**Clinical criteria:**

- The treatment must be for when all other anti-depressant therapy has failed; OR
- The treatment must be for when all other anti-depressant therapy is inappropriate.

**phenelzine 15 mg tablet, 100**

2856H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 91.99 | 38.80 | Nardil [LM] |

## ▪ TRANYLCYPROMINE

**Caution** This drug is an irreversible monoamine oxidase inhibitor.

**tranylcypromine 10 mg tablet, 50**

2444P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 55.92 | 38.80 | Parnate [GH] |

*Monoamine oxidase A inhibitors*

## ▪ MOCLOBEMIDE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

**moclobemide 300 mg tablet, 60**

8003F

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 27.36 | 28.57 | [a] Amira 300 [AF]<br>[a] GenRx Moclobemide [GX]<br>[a] Moclobemide Sandoz [SZ] | [a] Clobemix [ED]<br>[a] Moclobemide AN [EA] |
| | | [B]3.00 | 30.36 | 28.57 | [a] Aurorix 300 mg [HM] | |

**moclobemide 150 mg tablet, 60**

1900B

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 20.83 | 22.04 | [a] Amira 150 [AF]<br>[a] GenRx Moclobemide [GX]<br>[a] Moclobemide Sandoz [SZ] | [a] Clobemix [ED]<br>[a] Moclobemide AN [EA]<br>[a] Mohexal [HX] |
| | | [B]3.00 | 23.83 | 22.04 | [a] Aurorix [HM] | |

*Other antidepressants*

## ▪ DESVENLAFAXINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 50 mg, desvenlafaxine tablet (modified release) 50 mg (as benzoate) and desvenlafaxine tablet (extended release) 50 mg (as succinate) are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 100 mg, desvenlafaxine tablet (modified release) 100 mg (as benzoate) and desvenlafaxine tablet (extended release) 100 mg (as succinate) are equivalent for the purposes of substitution.

**Restricted benefit**

Major depressive disorders

**desvenlafaxine 50 mg modified release tablet, 28**

10234P

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 25.36 | 26.57 | [a] APO-Desvenlafaxine MR [TX] | [a] Desvenlafaxine GH XR [GQ] |

**desvenlafaxine 50 mg modified release tablet, 28**

10241B

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 25.36 | 26.57 | [a] Desfax [AF] | [a] DESVEN [RW] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Desvenlafaxine Actavis [EA] | [a] Desvenlafaxine Sandoz [SZ] |

**desvenlafaxine 50 mg modified release tablet, 28**

| 9366Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 25.36 | 26.57 | [a] Pristiq [PF] | |

**desvenlafaxine 100 mg modified release tablet, 28**

| 10231L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 28.61 | 29.82 | [a] Desfax [AF]<br>[a] Desvenlafaxine Actavis [EA] | [a] DESVEN [RW]<br>[a] Desvenlafaxine Sandoz [SZ] |

**desvenlafaxine 100 mg modified release tablet, 28**

| 10245F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 28.61 | 29.82 | [a] APO-Desvenlafaxine MR [TX] | [a] Desvenlafaxine GH XR [GQ] |

**desvenlafaxine 100 mg modified release tablet, 28**

| 9367B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 28.61 | 29.82 | [a] Pristiq [PF] |

## ▪ DULOXETINE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
Major depressive disorders

**duloxetine 60 mg enteric capsule, 28**

| 9156X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.01 | 18.22 | [a] Andepra [EL]<br>[a] Chem mart Duloxetine [CH]<br>[a] Duloxetine AN [EA]<br>[a] DYTREX 60 [RW]<br>[a] Terry White Chemists Duloxetine [TW] | [a] APO-Duloxetine [TX]<br>[a] Depreta 60 [DO]<br>[a] Duloxetine GH [GQ]<br>[a] Pharmacor Duloxetine 60 [CR]<br>[a] Tixol [AL] |
| | | | [B]1.91 | 18.92 | 18.22 | [a] Cymbalta [LY] | |

**duloxetine 30 mg enteric capsule, 28**

| 9155W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 15.24 | 16.45 | [a] Andepra [EL]<br>[a] Chem mart Duloxetine [CH]<br>[a] Duloxetine AN [EA]<br>[a] DYTREX 30 [RW]<br>[a] Terry White Chemists Duloxetine [TW] | [a] APO-Duloxetine [TX]<br>[a] Depreta 30 [DO]<br>[a] Duloxetine GH [GQ]<br>[a] Pharmacor Duloxetine 30 [CR]<br>[a] Tixol [AL] |
| | | | [B]1.90 | 17.14 | 16.45 | [a] Cymbalta [LY] | |

## ▪ LITHIUM CARBONATE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**lithium carbonate 450 mg modified release tablet, 100**

| 8290H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | .. | *35.57 | 36.78 | Quilonum SR [AS] |

**lithium carbonate 250 mg tablet, 200**

| 3059B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 23.19 | 24.40 | Lithicarb [AS] |

## ▪ MIANSERIN

**Caution** Neutropenia and agranulocytosis are more frequent in the elderly, especially in the early months of therapy.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Severe depression

**mianserin hydrochloride 20 mg tablet, 50**

| 1628Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 27.54 | 28.75 | Lumin 20 [AF] |

**mianserin hydrochloride 10 mg tablet, 50**

| 1627P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 18.89 | 20.10 | Lumin 10 [AF] |

## ▪ MIRTAZAPINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

**mirtazapine 30 mg tablet, 30**

| 8513C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.69 | 15.90 | [a] APO-Mirtazapine [TX]<br>[a] Axit 30 [AF]<br>[a] MIRTANZA [RF]<br>[a] Mirtazapine-GA [ED]<br>[a] Mirtazapine Sandoz [SZ]<br>[a] Terry White Chemists Mirtazapine [TW] | [a] Aurozapine 30 [DO]<br>[a] Chem mart Mirtazapine [CH]<br>[a] Mirtazapine AN [EA]<br>[a] Mirtazapine GH [GQ]<br>[a] Mirtazon [RW] |
| | | | [B]4.20 | 18.89 | 15.90 | [a] Avanza [MK] | |

**MIRTAZAPINE Tablet 30 mg (orally disintegrating), 30**

| 8856D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.61 | 17.82 | [a] Milivin OD 30 [DO]<br>[a] Mirtazapine Sandoz ODT 30 [SZ] | [a] Mirtazapine AN ODT [EA] |
| | | | [B]4.75 | 21.36 | 17.82 | [a] Avanza SolTab [MK] | [a] Remeron SolTab [AF] |

**mirtazapine 45 mg tablet, 30**

| 8883M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.09 | 18.30 | [a] APO-Mirtazapine [TX]<br>[a] Axit 45 [AF]<br>[a] MIRTANZA [RF]<br>[a] Mirtazapine-GA [ED]<br>[a] Mirtazapine Sandoz [SZ]<br>[a] Terry White Chemists Mirtazapine [TW] | [a] Aurozapine 45 [DO]<br>[a] Chem mart Mirtazapine [CH]<br>[a] Mirtazapine AN [EA]<br>[a] Mirtazapine GH [GQ]<br>[a] Mirtazon [RW] |
| | | | [B]4.20 | 21.29 | 18.30 | [a] Avanza [MK] | |

**MIRTAZAPINE Tablet 15 mg (orally disintegrating), 30**

| 8855C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.23 | 16.44 | [a] Milivin OD 15 [DO]<br>[a] Mirtazapine Sandoz ODT 15 [SZ] | [a] Mirtazapine AN ODT [EA] |
| | | | [B]4.75 | 19.98 | 16.44 | [a] Avanza SolTab [MK] | [a] Remeron SolTab [AF] |

**mirtazapine 15 mg tablet, 30**

| 9365X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 13.49 | 14.70 | [a] APO-Mirtazapine [TX]<br>[a] MIRTANZA [RF] | [a] Axit 15 [AF]<br>[a] Mirtazapine AN [EA] |

**MIRTAZAPINE Tablet 45 mg (orally disintegrating), 30**

| 8857E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 19.39 | 20.60 | [a] Milivin OD 45 [DO]<br>[a] Mirtazapine Sandoz ODT 45 [SZ] | [a] Mirtazapine AN ODT [EA] |
| | | | [B]4.75 | 24.14 | 20.60 | [a] Avanza SolTab [MK] | [a] Remeron SolTab [AF] |

## ▪ REBOXETINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

**reboxetine 4 mg tablet, 60**

| 8583R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 37.80 | 38.80 | Edronax [PF] |

## ▪ VENLAFAXINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

**venlafaxine 37.5 mg modified release capsule, 28**

| 8868R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 13.48 | 14.69 | [a] Efexor-XR [PF]<br>[a] Venlafaxine AN SR [EA] | [a] Elaxine SR 37.5 [ZP] |

**venlafaxine 150 mg modified release capsule, 28**

| 8302Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.48 | 16.69 | [a] APO-Venlafaxine XR [TX] | [a] Blooms the Chemist Venlafaxine XR [IB] |
| | | | | | | [a] Chem mart Venlafaxine XR [CH] | [a] Efexor-XR [PF] |
| | | | | | | [a] Elaxine SR 150 [ZP] | [a] Enlafax-XR [AF] |
| | | | | | | [a] Terry White Chemists Venlafaxine XR [TW] | [a] Venlafaxine AN SR [EA] |
| | | | | | | [a] Venlafaxine generichealth XR [GQ] | [a] Venlafaxine Sandoz XR [SZ] |
| | | | | | | [a] Venla RBX [RA] | |

**venlafaxine 75 mg modified release capsule, 28**

| 8301X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 14.69 | 15.90 | [a] APO-Venlafaxine XR [TX] | [a] Blooms the Chemist Venlafaxine XR [IB] |
| | | | | | | [a] Chem mart Venlafaxine XR [CH] | [a] Efexor-XR [PF] |
| | | | | | | [a] Elaxine SR 75 [ZP] | [a] Enlafax-XR [AF] |
| | | | | | | [a] Terry White Chemists Venlafaxine XR [TW] | [a] Venlafaxine AN SR [EA] |
| | | | | | | [a] Venlafaxine generichealth XR [GQ] | [a] Venlafaxine Sandoz XR [SZ] |

# PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS

*Centrally acting sympathomimetics*

## ▪ ARMODAFINIL

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** This drug is not PBS-subsidised when used in combination with PBS-subsidised dexamphetamine sulphate or modafinil.

**Authority required**

Narcolepsy

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a qualified sleep medicine practitioner or neurologist.

**Clinical criteria:**

- The treatment must be for use when therapy with dexamphetamine sulfate poses an unacceptable medical risk; OR
- The treatment must be for use when intolerance to dexamphetamine sulfate is of a severity to necessitate treatment withdrawal, **AND**

- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, **AND**
- Patient must have a definite history of cataplexy; OR
- Patient must have a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT); OR
- Patient must have an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep, **AND**
- Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The presence of any one of the following indicates treatment with dexamphetamine sulfate poses an unacceptable medical risk:

(a) a psychiatric disorder;

(b) a cardiovascular disorder;

(c) a history of substance abuse;

(d) glaucoma;

(e) any other absolute contraindication to dexamphetamine sulfate as specified in the TGA-approved Product Information.

The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration.

The authority application must be made in writing and must include the following:

(a) a completed authority prescription form; and

(b) a completed Narcolepsy Initial PBS authority application and Supporting information form; and

(c) details of the contraindication or intolerance to dexamphetamine sulfate; and

(d) either:

(i) the result and date of the polysomnography test and Multiple Sleep Latency Test (MSLT) conducted by, or under the supervision of, a qualified sleep medicine practitioner; or

(ii) the result and date of the electroencephalograph (EEG), conducted by, or under the supervision of, a neurologist.

The polysomnography, MSLT or EEG test reports must be provided with the authority application.

**Authority required**

Narcolepsy

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**armodafinil 50 mg tablet, 30**

| 10922W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *105.93 | 38.80 | Nuvigil [TB] |

**armodafinil 250 mg tablet, 30**

| 10919Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 250.17 | 38.80 | Nuvigil [TB] |

**armodafinil 150 mg tablet, 30**

| 10912H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 153.34 | 38.80 | Nuvigil [TB] |

## ▪ ATOMOXETINE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***4578***

Attention deficit hyperactivity disorder

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug.

**Authority required (STREAMLINED)**

***6279***

Attention deficit hyperactivity disorder

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be or have been diagnosed by a paediatrician or psychiatrist according to the DSM-5 criteria, **AND**
- Patient must have a contraindication to dexamphetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; OR
- Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamphetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; OR
- Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR

- Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamphetamine, methylphenidate and lisdexamfetamine (not simultaneously).

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**atomoxetine 10 mg capsule, 28**

9092M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *168.11 | 38.80 | [a] APO-Atomoxetine [TX]<br>[a] Atomoxetine Amneal [EA]<br>[a] Strattera [LY] | [a] ATOMERRA [RW]<br>[a] Atomoxetine Sandoz [SZ] |

## ▪ ATOMOXETINE

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***6279***

Attention deficit hyperactivity disorder

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be or have been diagnosed by a paediatrician or psychiatrist according to the DSM-5 criteria, **AND**
- Patient must have a contraindication to dexamphetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; OR
- Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamphetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; OR
- Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR
- Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamphetamine, methylphenidate and lisdexamfetamine (not simultaneously).

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**Authority required (STREAMLINED)**

***4578***

Attention deficit hyperactivity disorder

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug.

**atomoxetine 100 mg capsule, 28**

9290Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 113.15 | 38.80 | [a] APO-Atomoxetine [TX]<br>[a] Atomoxetine Amneal [EA]<br>[a] Strattera [LY] | [a] ATOMERRA [RW]<br>[a] Atomoxetine Sandoz [SZ] |

**atomoxetine 18 mg capsule, 28**

9093N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *168.11 | 38.80 | [a] APO-Atomoxetine [TX]<br>[a] Atomoxetine Amneal [EA]<br>[a] Strattera [LY] | [a] ATOMERRA [RW]<br>[a] Atomoxetine Sandoz [SZ] |

**atomoxetine 60 mg capsule, 28**

9096R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *168.11 | 38.80 | [a] APO-Atomoxetine [TX]<br>[a] Atomoxetine Amneal [EA]<br>[a] Strattera [LY] | [a] ATOMERRA [RW]<br>[a] Atomoxetine Sandoz [SZ] |

**atomoxetine 25 mg capsule, 28**

9094P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *168.11 | 38.80 | [a] APO-Atomoxetine [TX]<br>[a] Atomoxetine Amneal [EA]<br>[a] Strattera [LY] | [a] ATOMERRA [RW]<br>[a] Atomoxetine Sandoz [SZ] |

**atomoxetine 80 mg capsule, 28**

9289X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 113.15 | 38.80 | [a] APO-Atomoxetine [TX]<br>[a] Atomoxetine Amneal [EA]<br>[a] Strattera [LY] | [a] ATOMERRA [RW]<br>[a] Atomoxetine Sandoz [SZ] |

**atomoxetine 40 mg capsule, 28**

| 9095Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *168.11 | 38.80 | [a] APO-Atomoxetine [TX]<br>[a] Atomoxetine Amneal [EA]<br>[a] Strattera [LY] | [a] ATOMERRA [RW]<br>[a] Atomoxetine Sandoz [SZ] |

## ▪ DEXAMFETAMINE

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Attention deficit hyperactivity disorder

Treatment must be in accordance with the law of the relevant State or Territory.

**Authority required**

Narcolepsy

**dexamfetamine sulfate 5 mg tablet, 100**

| 1165H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 21.58 | 22.79 | Aspen Pharma Pty Ltd [QA] |

## ▪ LISDEXAMFETAMINE

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Attention deficit hyperactivity disorder

**Clinical criteria:**

- Patient must require continuous coverage over 12 hours.

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**lisdexamfetamine dimesilate 50 mg capsule, 30**

| 10474G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 117.10 | 38.80 | Vyvanse [ZI] |

**lisdexamfetamine dimesilate 70 mg capsule, 30**

| 10492F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 117.10 | 38.80 | Vyvanse [ZI] |

**lisdexamfetamine dimesilate 30 mg capsule, 30**

| 10486X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 117.10 | 38.80 | Vyvanse [ZI] |

## ▪ METHYLPHENIDATE

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Attention deficit hyperactivity disorder

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**Clinical criteria:**

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 12 hours.

**methylphenidate hydrochloride 18 mg modified release tablet, 30**

| 2387P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 51.79 | 38.80 | Concerta [JC] |

**methylphenidate hydrochloride 27 mg modified release tablet, 30**

| 2172H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 55.93 | 38.80 | Concerta [JC] |

**methylphenidate hydrochloride 36 mg modified release tablet, 30**

| 2388Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 60.06 | 38.80 | Concerta [JC] |

**methylphenidate hydrochloride 54 mg modified release tablet, 30**

| 2432B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 69.21 | 38.80 | Concerta [JC] |

## ▪ METHYLPHENIDATE

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Attention deficit hyperactivity disorder

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**Clinical criteria:**

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 8 hours.

**methylphenidate hydrochloride 40 mg modified release capsule, 30**

| 2283E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 55.03 | 38.80 | Ritalin LA [NV] |

**methylphenidate hydrochloride 20 mg modified release capsule, 30**

| 2276T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 45.04 | 38.80 | Ritalin LA [NV] |

**methylphenidate hydrochloride 10 mg modified release capsule, 30**

| 3440C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 35.77 | 36.98 | Ritalin LA [NV] |

**methylphenidate hydrochloride 30 mg modified release capsule, 30**

| 2280B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 52.50 | 38.80 | Ritalin LA [NV] |

## ▪ METHYLPHENIDATE

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Attention deficit hyperactivity disorder

Treatment must be in accordance with the law of the relevant State or Territory.

**methylphenidate hydrochloride 10 mg tablet, 100**

| 8839F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 21.63 | 22.84 | [a] Artige [NM] | [a] Ritalin 10 [NV] |

## ▪ MODAFINIL

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** This drug is not PBS-subsidised when used in combination with PBS-subsidised dexamphetamine sulphate or armodafinil.

**Authority required**

Narcolepsy

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a qualified sleep medicine practitioner or neurologist.

**Clinical criteria:**

- The treatment must be for use when therapy with dexamphetamine sulfate poses an unacceptable medical risk; OR
- The treatment must be for use when intolerance to dexamphetamine sulfate is of a severity to necessitate treatment withdrawal, **AND**
- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, **AND**
- Patient must have a definite history of cataplexy; OR
- Patient must have a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT); OR
- Patient must have an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep, **AND**
- Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The presence of any one of the following indicates treatment with dexamphetamine sulfate poses an unacceptable medical risk:

(a) a psychiatric disorder;

(b) a cardiovascular disorder;

(c) a history of substance abuse;

(d) glaucoma;

(e) any other absolute contraindication to dexamphetamine sulfate as specified in the TGA-approved Product Information.

The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration.

The authority application must be made in writing and must include the following:

(a) a completed authority prescription form; and

(b) a completed Narcolepsy Initial PBS authority application and Supporting information form; and

(c) details of the contraindication or intolerance to dexamphetamine sulfate; and

(d) either:

(i) the result and date of the polysomnography test and Multiple Sleep Latency Test (MSLT) conducted by, or under the supervision of, a qualified sleep medicine practitioner; or

(ii) the result and date of the electroencephalograph (EEG), conducted by, or under the supervision of, a neurologist.

The polysomnography, MSLT or EEG test reports must be provided with the authority application.

**Authority required**

Narcolepsy

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**modafinil 100 mg tablet, 60**

8816B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *285.23 | 38.80 | [a] APO-Modafinil [TX] | [a] Modafin [RW] |
| | | | | | [a] Modafinil AN [EA] | [a] Modafinil Mylan [AF] |
| | | | | | [a] Modafinil Sandoz [SZ] | [a] Modavigil [TB] |

## ANTI-DEMENTIA DRUGS

*Anticholinesterases*

### ▪ DONEPEZIL

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4219***

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**

- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**donepezil hydrochloride 5 mg tablet, 28**

| 2532G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 21.15 | 22.36 | [a] APO-Donepezil [TX]<br>[a] Aridon 5 [RW]<br>[a] Chem mart Donepezil [CH]<br>[a] Donepezil-DRLA [RZ]<br>[a] Donepezil generichealth [GQ]<br>[a] Donepezil Sandoz [SZ] | [a] Arazil [AF]<br>[a] Aridon APN 5 [RF]<br>[a] Donepezil AN [EA]<br>[a] Donepezil-GA [ED]<br>[a] Donepezil RBX [RA]<br>[a] Terry White Chemists Donepezil [TW] |
| | | | [B]3.68 | 24.83 | 22.36 | [a] Aricept [PF] | |

**donepezil hydrochloride 10 mg tablet, 28**

| 2479L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 21.15 | 22.36 | [a] APO-Donepezil [TX]<br>[a] Aridon 10 [RW]<br>[a] Chem mart Donepezil [CH]<br>[a] Donepezil-DRLA [RZ]<br>[a] Donepezil generichealth [GQ]<br>[a] Donepezil Sandoz [SZ]<br>[a] Terry White Chemists Donepezil [TW] | [a] Arazil [AF]<br>[a] Aridon APN 10 [RF]<br>[a] Donepezil AN [EA]<br>[a] Donepezil-GA [ED]<br>[a] Donepezil RBX [RA]<br>[a] Pharmacor Donepezil 10 [CR] |
| | | | [B]3.68 | 24.83 | 22.36 | [a] Aricept [PF] | |

## ▪ DONEPEZIL

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

**Authority required**

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;

(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;

(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;

(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;

(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;

(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

**donepezil hydrochloride 5 mg tablet, 28**

| 8495D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 21.15 | 22.36 | [a] APO-Donepezil [TX]<br>[a] Aridon 5 [RW]<br>[a] Chem mart Donepezil [CH]<br>[a] Donepezil-DRLA [RZ]<br>[a] Donepezil generichealth [GQ]<br>[a] Donepezil Sandoz [SZ] | [a] Arazil [AF]<br>[a] Aridon APN 5 [RF]<br>[a] Donepezil AN [EA]<br>[a] Donepezil-GA [ED]<br>[a] Donepezil RBX [RA]<br>[a] Terry White Chemists Donepezil [TW] |
| | | | [B]3.68 | 24.83 | 22.36 | [a] Aricept [PF] | |

**donepezil hydrochloride 10 mg tablet, 28**

| 8496E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 21.15 | 22.36 | [a] APO-Donepezil [TX]<br>[a] Aridon 10 [RW]<br>[a] Chem mart Donepezil [CH]<br>[a] Donepezil-DRLA [RZ]<br>[a] Donepezil generichealth [GQ]<br>[a] Donepezil Sandoz [SZ]<br>[a] Terry White Chemists Donepezil [TW] | [a] Arazil [AF]<br>[a] Aridon APN 10 [RF]<br>[a] Donepezil AN [EA]<br>[a] Donepezil-GA [ED]<br>[a] Donepezil RBX [RA]<br>[a] Pharmacor Donepezil 10 [CR] |
| | | | [B]3.68 | 24.83 | 22.36 | [a] Aricept [PF] | |

## ▪ GALANTAMINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4219***

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**galantamine 8 mg modified release capsule, 28**

| 2463P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 32.97 | 34.18 | [a] APO-Galantamine MR [TX]<br>[a] Galantyl [AF] | [a] Galantamine AN SR [EA]<br>[a] Gamine XR [RW] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Reminyl [JC] | |

**galantamine 24 mg modified release capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2531F NP | 1 | 5 | .. | 42.98 | 38.80 | [a] APO-Galantamine MR [TX]<br>[a] Galantyl [AF]<br>[a] Reminyl [JC] | [a] Galantamine AN SR [EA]<br>[a] Gamine XR [RW] |

**galantamine 16 mg modified release capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2537M NP | 1 | 5 | .. | 37.85 | 38.80 | [a] APO-Galantamine MR [TX]<br>[a] Galantyl [AF]<br>[a] Reminyl [JC] | [a] Galantamine AN SR [EA]<br>[a] Gamine XR [RW] |

## ▪ GALANTAMINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

**Authority required**

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;

(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;

(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;

(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;

(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;

(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

**galantamine 8 mg modified release capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8770N NP | 1 | 5 | .. | 32.97 | 34.18 | [a] APO-Galantamine MR [TX]<br>[a] Galantyl [AF] | [a] Galantamine AN SR [EA]<br>[a] Gamine XR [RW] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Reminyl [JC] | |

**galantamine 24 mg modified release capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8772Q NP | 1 | 5 | .. | 42.98 | 38.80 | [a] APO-Galantamine MR [TX]<br>[a] Galantyl [AF]<br>[a] Reminyl [JC] | [a] Galantamine AN SR [EA]<br>[a] Gamine XR [RW] |

**galantamine 16 mg modified release capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8771P NP | 1 | 5 | .. | 37.85 | 38.80 | [a] APO-Galantamine MR [TX]<br>[a] Galantyl [AF]<br>[a] Reminyl [JC] | [a] Galantamine AN SR [EA]<br>[a] Gamine XR [RW] |

## ▪ RIVASTIGMINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4219***

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**rivastigmine 4.6 mg/24 hours patch, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2477J NP | 1 | 5 | .. | 80.59 | 38.80 | [a] Exelon Patch 5 [NV] | [a] Rivastigmelon Patch 5 [AF] |

**rivastigmine 13.3 mg/24 hours patch, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10538P NP | 1 | 5 | .. | 80.59 | 38.80 | Exelon Patch 15 [NV] |

**rivastigmine 1.5 mg capsule, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2475G NP | 1 | 5 | .. | 88.31 | 38.80 | Exelon [NV] |

**rivastigmine 6 mg capsule, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2526Y NP | 1 | 5 | .. | 88.31 | 38.80 | Exelon [NV] |

**rivastigmine 9.5 mg/24 hours patch, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2551G NP | 1 | 5 | .. | 80.59 | 38.80 | [a] Exelon Patch 10 [NV] | [a] Rivastigmelon Patch 10 [AF] |

**rivastigmine 3 mg capsule, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2493F NP | 1 | 5 | .. | 88.31 | 38.80 | Exelon [NV] |

**rivastigmine 4.5 mg capsule, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2494G NP | 1 | 5 | .. | 88.31 | 38.80 | Exelon [NV] |

## ▪ RIVASTIGMINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

**Authority required**

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;

(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;

(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;

(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;

(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;

(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

### rivastigmine 4.6 mg/24 hours patch, 30

| 9161E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 80.59 | 38.80 | [a] Exelon Patch 5 [NV] | [a] Rivastigmelon Patch 5 [AF] |

### rivastigmine 13.3 mg/24 hours patch, 30

| 10541T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 80.59 | 38.80 | Exelon Patch 15 [NV] |

### rivastigmine 1.5 mg capsule, 56

| 8497F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 88.31 | 38.80 | Exelon [NV] |

### rivastigmine 6 mg capsule, 56

| 8500J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 88.31 | 38.80 | Exelon [NV] |

**rivastigmine 9.5 mg/24 hours patch, 30**

| 9162F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 80.59 | 38.80 | [a] Exelon Patch 10 [NV] | [a] Rivastigmelon Patch 10 [AF] |

**rivastigmine 3 mg capsule, 56**

| 8498G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 88.31 | 38.80 | Exelon [NV] |

**rivastigmine 4.5 mg capsule, 56**

| 8499H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 88.31 | 38.80 | Exelon [NV] |

*Other anti-dementia drugs*

## ▪ MEMANTINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4214***

Moderately severe Alzheimer disease

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**memantine hydrochloride 20 mg tablet, 28**

| 2513G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 41.29 | 38.80 | [a] APO-Memantine [TX]<br>[a] Memantine generichealth [GQ] | [a] Ebixa [LU]<br>[a] Memantine RBX [RA] |

**memantine hydrochloride 10 mg tablet, 56**

| 2492E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 41.29 | 38.80 | [a] APO-Memantine [TX]<br>[a] Memantine generichealth [GQ]<br>[a] Memanxa [RW] | [a] Ebixa [LU]<br>[a] Memantine RBX [RA] |

## ▪ MEMANTINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 to 14, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE of 10 to 14.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

**Authority required**

Moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 to 14 for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;

(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;

(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;

(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;

(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;

(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

**memantine hydrochloride 20 mg tablet, 28**

| 9306T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 41.29 | 38.80 | [a] APO-Memantine [TX]<br>[a] Memantine generichealth [GQ] | [a] Ebixa [LU]<br>[a] Memantine RBX [RA] |

**memantine hydrochloride 10 mg tablet, 56**

| 1956Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 41.29 | 38.80 | [a] APO-Memantine [TX]<br>[a] Memantine generichealth [GQ]<br>[a] Memanxa [RW] | [a] Ebixa [LU]<br>[a] Memantine RBX [RA] |

## OTHER NERVOUS SYSTEM DRUGS

### PARASYMPATHOMIMETICS

*Anticholinesterases*

### PYRIDOSTIGMINE

**PYRIDOSTIGMINE BROMIDE Tablet 10 mg, 50**

| 2724J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *24.79 | 26.00 | Mestinon [IA] |

**pyridostigmine bromide 60 mg tablet, 150**

| 1959D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 67.14 | 38.80 | Mestinon [IA] |

**pyridostigmine bromide 180 mg modified release tablet, 50**

| 2608G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *134.41 | 38.80 | Mestinon Timespan [IA] |

*Choline esters*

### BETHANECHOL

**bethanechol chloride 10 mg tablet, 100**

| 1062X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 37.92 | 38.80 | Uro-Carb [YN] |

## DRUGS USED IN ADDICTIVE DISORDERS

*Drugs used in nicotine dependence*

### ▪ BUPROPION

**Note** Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.
**Note** The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***6881***

Nicotine dependence

Treatment Phase: Completion of a short-term (9 weeks) course of treatment

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment, **AND**
- Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

**bupropion hydrochloride 150 mg modified release tablet, 90**

8710K (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 165.40 | 38.80 | Zyban [AS] |

### ▪ BUPROPION

**Note** Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.
**Note** The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months.
**Note** A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***6882***

Nicotine dependence

Treatment Phase: Commencement of a short-term (9 weeks) course of treatment

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

**bupropion hydrochloride 150 mg modified release tablet, 30**

8465M (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 62.53 | 38.80 | Zyban [AS] |

### ▪ NICOTINE

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Nicotine dependence

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

**nicotine 21 mg/24 hours patch, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3414Q NP | 1 | 2 | .. | 53.17 | 38.80 | Nicotinell Step 1 [ON] |

**nicotine 14 mg/24 hours patch, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5572G NP | 1 | 2 | .. | 53.17 | 38.80 | Nicotinell Step 2 [ON] |

**nicotine 7 mg/24 hours patch, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5573H NP | 1 | 2 | .. | 53.17 | 38.80 | Nicotinell Step 3 [ON] |

## ▪ NICOTINE

**Note** Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period. Benefit is improved if used in conjunction with a comprehensive support and counselling program.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Nicotine dependence

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition.

**nicotine 21 mg/24 hours patch, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5571F NP | 1 | 2 | .. | 53.17 | 38.80 | Nicotinell Step 1 [ON] |

## ▪ NICOTINE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Nicotine dependence

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period. Benefit is improved if used in conjunction with a comprehensive support and counselling program.

**Restricted benefit**

Nicotine dependence

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

**nicotine 25 mg/16 hours patch, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10076H NP | 1 | 2 | .. | 53.17 | 38.80 | nicorette 16hr Invisipatch [JT] |

**nicotine 21 mg/24 hours patch, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5465P NP | 1 | 2 | .. | 53.17 | 38.80 | Nicabate P [GC] |

## ▪ VARENICLINE

**Note** A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

**Note** A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***6885***

Nicotine dependence

Treatment Phase: Completion of a short-term (24 weeks) course of treatment

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment, **AND**
- Patient must have ceased smoking in the process of completing an initial 12-weeks or ceased smoking following an initial 12-weeks of PBS-subsidised treatment with this drug in the current course of treatment.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

**varenicline 1 mg tablet, 56**

5469W

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 109.55 | 38.80 | Champix [PF] |

## ▪ VARENICLINE

**Note** A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

**Note** A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***6864***

Nicotine dependence

Treatment Phase: Continuation of a short-term (12 weeks or 24 weeks) course of treatment

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

**varenicline 1 mg tablet, 56**

9129L

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *208.61 | 38.80 | Champix [PF] |

## ▪ VARENICLINE

**Note** A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

**Note** The period between commencing varenicline and bupropion or a new course of varenicline must be at least 6 months.

**Note** A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***6871***

Nicotine dependence

Treatment Phase: Commencement of a short-term (12 weeks or 24 weeks) course of treatment

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 24 weeks of PBS-subsidised treatment with this drug per 12-month period.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested.

**varenicline 500 microgram tablet [11 tablets] (&) varenicline 1 mg tablet [42 tablets], 53**

| 9128K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | .. | .. | 94.60 | 38.80 | Champix [PF] |

*Drugs used in alcohol dependence*

## ▪ ACAMPROSATE

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**
***5366***
Alcohol dependence
**Clinical criteria:**

- The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence.

**acamprosate calcium 333 mg enteric tablet, 180**

| 8357W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 149.41 | 38.80 | Campral [AF] |

## ▪ NALTREXONE

**Caution** Naltrexone hydrochloride is contraindicated in patients receiving opioid drugs.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**
Alcohol dependence
**Clinical criteria:**

- The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence.

**naltrexone hydrochloride 50 mg tablet, 30**

| 8370M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 128.59 | 38.80 | [a] APO-Naltrexone [TX]<br>[a] ReVia [BQ] | [a] Naltrexone GH [GQ] |

## OTHER NERVOUS SYSTEM DRUGS

*Other nervous system drugs*

## ▪ DIMETHYL FUMARATE

**Note** Special Pricing Arrangements apply.

**Authority required**
Multiple sclerosis
Treatment Phase: Continuing treatment
**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**dimethyl fumarate 120 mg enteric capsule, 14**

| 2943X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *969.23 | 38.80 | Tecfidera [BD] |

## ▪ DIMETHYL FUMARATE

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**
Multiple sclerosis
Treatment Phase: Continuing treatment
**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**dimethyl fumarate 240 mg enteric capsule, 56**

2966D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1871.14 | 38.80 | Tecfidera [BD] |

## ▪ DIMETHYL FUMARATE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**dimethyl fumarate 120 mg enteric capsule, 14**

2896K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *969.23 | 38.80 | Tecfidera [BD] |

## ▪ RILUZOLE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Amyotrophic lateral sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed by a neurologist, **AND**
- Patient must not have had the disease for more than 5 years, **AND**
- Patient must have at least 60 percent of predicted forced vital capacity within the 2 months before commencing therapy with this drug, **AND**
- Patient must be ambulatory; OR
- Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, **AND**
- Patient must not have undergone a tracheostomy, **AND**
- Patient must not have experienced respiratory failure.

The date of diagnosis and the date and results of spirometry (in terms of percent of predicted forced vital capacity) must be supplied with the initial authority application.

**Authority required**

Amyotrophic lateral sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must be ambulatory; OR
- Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, **AND**
- Patient must not have undergone a tracheostomy, **AND**
- Patient must not have experienced respiratory failure.

**riluzole 50 mg tablet, 56**

8664B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 203.32 | 38.80 | [a] APO-Riluzole [TX] | [a] Pharmacor Riluzole [CR] |

NP

[a] Rilutek [SW] [a] Riluzole Sandoz [SZ]

## ▪ TETRABENAZINE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***5340***
Hyperkinetic extrapyramidal disorders

**tetrabenazine 25 mg tablet, 112**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1330B NP | 1 | 5 | .. | 338.60 | 38.80 | iNova Pharmaceuticals (Australia) Pty Ltd [IA] |

# ▪ ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

# ▪ ANTIPROTOZOALS

## AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES

*Other agents against amoebiasis and other protozoal diseases*

## ▪ ATOVAQUONE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***5609***
Mild to moderate Pneumocystis carinii pneumonia
**Population criteria:**
- Patient must be an adult, **AND**
- Patient must be intolerant of trimethoprim/sulfamethoxazole therapy.

**atovaquone 750 mg/5 mL oral liquid, 210 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8300W NP | ‡1 | .. | .. | 976.85 | 38.80 | Wellvone [AS] |

## ▪ PYRIMETHAMINE

**pyrimethamine 25 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1966L NP | 1 | .. | .. | 19.32 | 20.53 | Daraprim [RW] |

## ANTIMALARIALS

*Biguanides*

## ▪ ATOVAQUONE + PROGUANIL

**Note** This drug is not PBS-subsidised for prophylaxis of malaria.
**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
Confirmed or suspected Plasmodium falciparum malaria
**Population criteria:**
- Patient must be aged 3 years or older.

**Clinical criteria:**
- The treatment must be used where quinine containing regimens are inappropriate.

**atovaquone 250 mg + proguanil hydrochloride 100 mg tablet, 12**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9439T NP | 1 | .. | .. | 66.16 | 38.80 | Malarone [GK] |

*Methanolquinolines*

## ▪ QUININE

**Caution** Severe thrombocytopenia has been reported with this drug.
**Authority required (STREAMLINED)**

***5633***
Malaria

**quinine sulfate 300 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1975Y NP | 1 | 2 | .. | 19.91 | 21.12 | Quinate [RW] |

*Artemisinin and derivatives, combinations*

## ▪ ARTEMETHER + LUMEFANTRINE

**Note** This drug is not PBS-subsidised for prophylaxis of malaria.

**Restricted benefit**
Confirmed or suspected Plasmodium falciparum malaria
**Clinical criteria:**

- Patient must be unable to swallow a solid dosage form of artemether with lumefantrine.

**artemether 20 mg + lumefantrine 120 mg dispersible tablet, 18**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5296R | 1 | .. | .. | 89.24 | 38.80 | Riamet 20mg/120mg Dispersible [SZ] |

## ▪ ARTEMETHER + LUMEFANTRINE

**Note** This drug is not PBS-subsidised for prophylaxis of malaria.

**Restricted benefit**
Confirmed or suspected Plasmodium falciparum malaria

**artemether 20 mg + lumefantrine 120 mg tablet, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9498X | 1 | .. | .. | 89.24 | 38.80 | Riamet [SZ] |

# ▪ ANTHELMINTICS

## ANTITREMATODALS

*Quinoline derivatives and related substances*

## ▪ PRAZIQUANTEL

**Authority required (STREAMLINED)**
***5659***
Schistosomiasis

**praziquantel 600 mg tablet, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9447F NP | 1 | .. | .. | 39.54 | 38.80 | Biltricide [BN] |

## ANTINEMATODAL AGENTS

*Benzimidazole derivatives*

## ▪ ALBENDAZOLE

**Authority required (STREAMLINED)**
***5607***
Hydatid disease
**Clinical criteria:**

- The treatment must be in conjunction with surgery; OR
- The treatment must be used when a surgical cure cannot be achieved; OR
- The treatment must be used when surgery cannot be used.

**albendazole 400 mg chewable tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8459F | 1 | 2 | .. | 165.53 | 38.80 | Eskazole [AS] |

## ▪ ALBENDAZOLE

**Authority required (STREAMLINED)**
***5680***
Tapeworm infestation

**albendazole 200 mg chewable tablet, 6**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8503M NP | 1 | 1 | .. | 33.13 | 34.34 | Zentel [AS] |

## ▪ ALBENDAZOLE

**Authority required (STREAMLINED)**

***5817***

Whipworm infestation

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**Authority required (STREAMLINED)**

***5712***

Strongyloidiasis

**Authority required (STREAMLINED)**

***5797***

Hookworm infestation

**albendazole 200 mg chewable tablet, 6**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9047E NP | 1 | .. | .. | 33.13 | 34.34 | Zentel [AS] |

*Tetrahydropyrimidine derivatives*

## ▪ PYRANTEL

**pyrantel 125 mg tablet, 6**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3047J NP | 1 | .. | .. | 17.84 | 19.05 | Anthel 125 [AF] |

**pyrantel 250 mg tablet, 6**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3048K NP | 1 | .. | .. | 24.61 | 25.82 | Anthel 250 [AF] |

*Avermectines*

## ▪ IVERMECTIN

**Authority required (STREAMLINED)**

***4319***

Onchocerciasis

**ivermectin 3 mg tablet, 4**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8359Y NP | 1 | .. | .. | 31.65 | 32.86 | Stromectol [MK] |

## ▪ IVERMECTIN

**Authority required (STREAMLINED)**

***4328***

Strongyloidiasis

**Authority required (STREAMLINED)**

***4565***

Crusted (Norwegian) scabies

**Clinical criteria:**

- The condition must be established by clinical and/or parasitological examination, **AND**
- Patient must be undergoing topical therapy for this condition; OR
- Patient must have a contraindication to topical treatment.

**Population criteria:**

- Patient must weigh 15 kg or over, **AND**
- Patient must be 5 years of age or older.

**Authority required (STREAMLINED)**

***4566***

Human sarcoptic scabies

**Clinical criteria:**

- The condition must be established by clinical and/or parasitological examination, **AND**
- Patient must have completed and failed sequential treatment with topical permethrin and benzyl benzoate and finished the most recent course of topical therapy at least 4 weeks prior to initiating oral therapy; OR
- Patient must have a contraindication to topical treatment.

**Population criteria:**

- Patient must weigh 15 kg or over, **AND**
- Patient must be 5 years of age or older.

**Note** This drug is not PBS-subsidised for first line treatment of typical scabies.

**ivermectin 3 mg tablet, 4**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2868Y NP | 2 | 2 | .. | *52.21 | 38.80 | Stromectol [MK] |

## ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS

### ECTOPARASITICIDES, INCL. SCABICIDES

*Pyrethrines, incl. synthetic compounds*

### PERMETHRIN

**permethrin 5% cream, 30 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3054R NP | ‡1 | 1 | .. | 19.64 | 20.85 | Lyclear [JT] |

## RESPIRATORY SYSTEM

## NASAL PREPARATIONS

### DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE

*Other nasal preparations*

### MUPIROCIN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**
***6647***
Staphylococcus aureus infection
**Clinical criteria:**
- Patient must have nasal colonisation with the bacteria.

**Population criteria:**
- Patient must be an Aboriginal or a Torres Strait Islander person.

**mupirocin 2% (20 mg/g) ointment, 3 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9440W NP | ‡1 | .. | .. | 22.84 | 24.05 | Bactroban [GK] |

## DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

### ADRENERGICS, INHALANTS

*Selective beta-2-adrenoreceptor agonists*

### EFORMOTEROL

**Restricted benefit**
Asthma
**Clinical criteria:**
- Patient must experience frequent episodes of the condition, **AND**
- Patient must be currently receiving treatment with oral corticosteroids; OR
- Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.

**eformoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8240Q NP | ‡1 | 5 | .. | 35.88 | 37.09 | Oxis Turbuhaler [AP] |

**eformoterol fumarate dihydrate 12 microgram powder for inhalation, 60 capsules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8136F NP | 1 | 5 | .. | 36.63 | 37.84 | Foradile [SZ] |

**eformoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8239P NP | ‡1 | 5 | .. | 27.58 | 28.79 | Oxis Turbuhaler [AP] |

### INDACATEROL

**Note** This drug is not PBS-subsidised for the treatment of asthma.

**Restricted benefit**
Chronic obstructive pulmonary disease (COPD)

**indacaterol 300 microgram powder for inhalation, 30 capsules**

| 5137J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 59.42 | 38.80 | Onbrez [NV] |

**indacaterol 150 microgram powder for inhalation, 30 capsules**

| 5134F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 59.42 | 38.80 | Onbrez [NV] |

## ▪ SALBUTAMOL

**salbutamol 100 microgram/actuation pressurised inhalation, 200 actuations**

| 8288F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *18.51 | 19.72 | [a] Asmol CFC-free [AL] |
| | | | [B]2.54 | *21.05 | 19.72 | [a] Ventolin CFC-free [GK] |

**salbutamol 200 microgram powder for inhalation, 128 capsules**

| 10143W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 4 | .. | *21.83 | 23.04 | Ventolin Rotacaps [GK] |

## ▪ SALBUTAMOL

**Restricted benefit**

Bronchospasm

**Clinical criteria:**

- Patient must be unable to achieve co-ordinated use of other metered dose inhalers containing this drug.

**salbutamol Oral pressurised inhalation in breath actuated device 100 micrograms (base) per dose (200 doses), CFC-free formulation, 1**

| 8354Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *39.07 | 38.80 | Airomir Autohaler [IA] |

## ▪ SALBUTAMOL

**Note** Pharmaceutical benefits that have a 30 x 2 pack size and a 20 x 3 pack size are equivalent for the purposes of substitution**.**

**Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

**salbutamol 5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules**

| 11095Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 5 | [B]0.99 | *20.50 | 20.72 | [a] Ventolin Nebules [GK] |

**salbutamol 2.5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules**

| 11130T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 5 | [B]1.02 | *20.11 | 20.30 | [a] Ventolin Nebules [GK] |

**salbutamol 5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules**

| 2001H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *19.51 | 20.72 | [a] APO-Salbutamol [TX]<br>[a] Salbutamol Actavis [EA] | [a] Butamol 5 [QA]<br>[a] Salbutamol Sandoz [SZ] |
| | | | [B]0.50 | *20.01 | 20.72 | [a] Asmol 5 uni-dose [AF] | |

**salbutamol 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules**

| 2000G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *19.09 | 20.30 | [a] APO-Salbutamol [TX]<br>[a] Salbutamol Actavis [EA] | [a] Butamol 2.5 [QA]<br>[a] Salbutamol Sandoz [SZ] |
| | | | [B]0.50 | *19.59 | 20.30 | [a] Asmol 2.5 uni-dose [AF] | |

## ▪ SALMETEROL

**Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must experience frequent episodes of the condition, **AND**

- Patient must be currently receiving treatment with oral corticosteroids; OR
- Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.

**salmeterol 50 microgram/actuation powder for inhalation, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8141L NP | ‡1 | 5 | .. | 36.63 | 37.84 | Serevent Accuhaler [GK] |

## ▪ TERBUTALINE

**terbutaline sulfate 500 microgram/actuation powder for inhalation, 100 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2817G NP | 2 | 5 | .. | *20.53 | 21.74 | Bricanyl Turbuhaler [AP] |

*Adrenergics in combination with corticosteroids or other drugs, excl. anticholinergics*

## ▪ BUDESONIDE + EFORMOTEROL

**Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

**Population criteria:**

- Patient must be aged 12 years or over.

**budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8796Y NP | ‡1 | 5 | .. | 54.64 | 38.80 | Symbicort Turbuhaler 100/6 [AP] |

**budesonide 200 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8625Y NP | ‡1 | 5 | .. | 58.68 | 38.80 | Symbicort Turbuhaler 200/6 [AP] |

## ▪ BUDESONIDE + EFORMOTEROL

**Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist.

**Population criteria:**

- Patient must be aged 12 years or over.

**budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation pressurised inhalation, 120 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10015D NP | 2 | 5 | .. | *56.29 | 38.80 | Symbicort Rapihaler 100/3 [AP] |

**budesonide 50 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation pressurised inhalation, 120 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10024N NP | 2 | 5 | .. | *52.47 | 38.80 | Symbicort Rapihaler 50/3 [AP] |

## ▪ BUDESONIDE + EFORMOTEROL

**Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**Note** Symbicort 400/12 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, **AND**
- Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- The treatment must be for symptomatic treatment.

**Note** Patient must not be on a concomitant single agent long-acting beta-2 agonist.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**budesonide 400 microgram/actuation + eformoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 120 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8750M NP | ‡1 | 5 | .. | 86.19 | 38.80 | Symbicort Turbuhaler 400/12 [AP] |

## ▪ BUDESONIDE + EFORMOTEROL

**Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**Note** Unlike Symbicort Turbuhaler 200/6, Symbicort Rapihaler 200/6 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy as the approved Product Information does not specify such use.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, **AND**
- Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- The treatment must be for symptomatic treatment.

**Note** Patient must not be on a concomitant single agent long-acting beta-2 agonist.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**budesonide 200 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation pressurised inhalation, 120 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10018G NP | 2 | 5 | .. | *82.45 | 38.80 | Symbicort Rapihaler 200/6 [AP] |

## ▪ FLUTICASONE + EFORMOTEROL

**Note** Flutiform is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** Flutiform is not indicated or PBS-subsidised for bronchodilator therapy in COPD.

**Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**fluticasone propionate 250 microgram/actuation + eformoterol fumarate dihydrate 10 microgram/actuation pressurised inhalation, 120 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10008R NP | ‡1 | 5 | .. | 64.07 | 38.80 | flutiform 250/10 [MF] |

**fluticasone propionate 50 microgram/actuation + eformoterol fumarate dihydrate 5 microgram/actuation pressurised inhalation, 120 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2827T NP | ‡1 | 5 | .. | 40.24 | 38.80 | flutiform 50/5 [MF] |

**fluticasone propionate 125 microgram/actuation + eformoterol fumarate dihydrate 5 microgram/actuation pressurised inhalation, 120 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10007Q NP | ‡1 | 5 | .. | 48.10 | 38.80 | flutiform 125/5 [MF] |

## ▪ FLUTICASONE + SALMETEROL

**Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 4 years or older.

**fluticasone propionate 100 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8430Q NP | ‡1 | 5 | .. | 41.56 | 38.80 | Seretide Accuhaler 100/50 [GK] |

**fluticasone propionate 125 microgram/actuation + salmeterol 25 microgram/actuation pressurised inhalation, 120 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8518H NP | ‡1 | 5 | .. | 48.25 | 38.80 | [a] Fluticasone + Salmeterol Cipla 125/25 [LR]<br>[a] Seretide MDI 125/25 [GK] | [a] SalplusF Inhaler 125/25 [YC] |

**fluticasone propionate 50 microgram/actuation + salmeterol 25 microgram/actuation pressurised inhalation, 120 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8517G NP | ‡1 | 5 | .. | 41.56 | 38.80 | Seretide MDI 50/25 [GK] |

**fluticasone propionate 250 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8431R NP | ‡1 | 5 | .. | 48.25 | 38.80 | Seretide Accuhaler 250/50 [GK] |

## ▪ FLUTICASONE + SALMETEROL

**Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 4 years or older.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, **AND**
- Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- The treatment must be for symptomatic treatment.

**Note** Patient must not be on a concomitant single agent long-acting beta-2 agonist.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8432T NP | ‡1 | 5 | .. | 61.39 | 38.80 | Seretide Accuhaler 500/50 [GK] |

**fluticasone propionate 250 microgram/actuation + salmeterol 25 microgram/actuation pressurised inhalation, 120 actuations**

| 8519J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 61.39 | 38.80 | [a] Fluticasone + Salmeterol Cipla 250/25 [LR]<br>[a] Seretide MDI 250/25 [GK] | [a] SalplusF Inhaler 250/25 [YC] |

## ▪ FLUTICASONE FUROATE + VILANTEROL

**Note** This drug is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.
**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Restricted benefit**
Asthma
**Clinical criteria:**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**
- Patient must be aged 12 years or over.

**fluticasone furoate 200 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

| 11129R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 71.62 | 38.80 | Breo Ellipta 200/25 [GK] |

## ▪ FLUTICASONE FUROATE + VILANTEROL

**Restricted benefit**
Asthma
**Clinical criteria:**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**
- Patient must be aged 12 years or over.

**Note** This drug is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

**Restricted benefit**
Chronic obstructive pulmonary disease (COPD)
**Clinical criteria:**
- Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, **AND**
- Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- The treatment must be for symptomatic treatment.

**Note** Patient must not be on a concomitant single agent long-acting beta-2 agonist.
**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**fluticasone furoate 100 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

| 11124L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 56.12 | 38.80 | Breo Ellipta 100/25 [GK] |

*Adrenergics in combination with anticholinergics*

## ▪ ACLIDINIUM + EFORMOTEROL

**Note** The treatment must not be used in combination with an ICS/LABA, or LAMA or LABA monotherapy.
**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
**Note** A LABA includes olodaterol, indacaterol, salmeterol, eformoterol or vilanterol.
**Note** This product is not PBS-subsidised for the treatment of asthma.
**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Authority required (STREAMLINED)**
***5763***
Chronic obstructive pulmonary disease (COPD)
**Clinical criteria:**
- Patient must have been stabilised on a combination of a long acting muscarinic antagonist and long acting beta-2 agonist.

**aclidinium 340 microgram/actuation + eformoterol fumarate dihydrate 12 microgram/actuation inhalation: powder for, 60 actuations**

| 10565C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 91.18 | 38.80 | Brimica Genuair [FK] |

## ▪ INDACATEROL + GLYCOPYRRONIUM

**Note** The treatment must not be used in combination with an ICS/LABA, or LAMA or LABA monotherapy.
**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
**Note** A LABA includes olodaterol, indacaterol, salmeterol, eformoterol or vilanterol.
**Note** This product is not PBS-subsidised for the treatment of asthma.
**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Authority required (STREAMLINED)**
***5763***
Chronic obstructive pulmonary disease (COPD)
**Clinical criteria:**

- Patient must have been stabilised on a combination of a long acting muscarinic antagonist and long acting beta-2 agonist.

**indacaterol 110 microgram + glycopyrronium 50 microgram powder for inhalation, 30 capsules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10156M NP | 1 | 5 | .. | 90.53 | 38.80 | ultibro breezhaler 110/50 [NV] |

## ▪ TIOTROPIUM + OLODATEROL

**Note** The treatment must not be used in combination with an ICS/LABA, or LAMA or LABA monotherapy.
**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
**Note** A LABA includes olodaterol, indacaterol, salmeterol, eformoterol or vilanterol.
**Note** This product is not PBS-subsidised for the treatment of asthma.
**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Authority required (STREAMLINED)**
***5763***
Chronic obstructive pulmonary disease (COPD)
**Clinical criteria:**

- Patient must have been stabilised on a combination of a long acting muscarinic antagonist and long acting beta-2 agonist.

**tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation solution, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10557P NP | ‡1 | 5 | .. | 90.01 | 38.80 | Spiolto Respimat [BY] |

## ▪ UMECLIDINIUM + VILANTEROL

**Note** The treatment must not be used in combination with an ICS/LABA, or LAMA or LABA monotherapy.
**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
**Note** A LABA includes olodaterol, indacaterol, salmeterol, eformoterol or vilanterol.
**Note** This product is not PBS-subsidised for the treatment of asthma.
**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Authority required (STREAMLINED)**
***5763***
Chronic obstructive pulmonary disease (COPD)
**Clinical criteria:**

- Patient must have been stabilised on a combination of a long acting muscarinic antagonist and long acting beta-2 agonist.

**umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10188F NP | ‡1 | 5 | .. | 92.56 | 38.80 | Anoro Ellipta 62.5/25 [GK] |

## OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS

*Glucocorticoids*

## ▪ BECLOMETASONE

**beclometasone dipropionate 50 microgram/actuation pressurised inhalation, 200 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8406K NP | ‡1 | 5 | .. | 21.72 | 22.93 | Qvar 50 [IA] |

**beclometasone dipropionate 100 microgram/actuation pressurised inhalation, 200 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8407L NP | ‡1 | 5 | .. | 33.43 | 34.64 | Qvar 100 [IA] |

## ▪ BECLOMETASONE

**Restricted benefit**
Asthma
**Clinical criteria:**

- Patient must be unable to achieve co-ordinated use of other metered dose inhalers containing this drug.

**BECLOMETHASONE DIPROPIONATE Oral pressurised inhalation in breath actuated device 100 micrograms per dose (200 doses), CFC-free formulation, 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8409N NP | ‡1 | 5 | .. | 38.11 | 38.80 | Qvar 100 Autohaler [IA] |

**BECLOMETHASONE DIPROPIONATE Oral pressurised inhalation in breath actuated device 50 micrograms per dose (200 doses), CFC-free formulation, 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8408M NP | ‡1 | 5 | .. | 28.81 | 30.02 | Qvar 50 Autohaler [IA] |

## ▪ BUDESONIDE

**budesonide 100 microgram/actuation powder for inhalation, 200 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2070Y NP | ‡1 | 5 | .. | 25.07 | 26.28 | Pulmicort Turbuhaler [AP] |

**budesonide 200 microgram/actuation powder for inhalation, 200 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2071B NP | ‡1 | 5 | .. | 31.45 | 32.66 | Pulmicort Turbuhaler [AP] |

**budesonide 400 microgram/actuation powder for inhalation, 200 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2072C NP | ‡1 | 5 | .. | 44.27 | 38.80 | Pulmicort Turbuhaler [AP] |

## ▪ BUDESONIDE

**Authority required (STREAMLINED)**

***6340***

Severe chronic asthma

**Clinical criteria:**

- Patient must require long-term steroid therapy, **AND**
- Patient must not be able to use other forms of inhaled steroid therapy.

**budesonide 500 microgram/2 mL inhalation solution, 30 x 2 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2065Q NP | ‡1 | 5 | .. | 37.07 | 38.28 | Pulmicort Respules [AP] |

**budesonide 1 mg/2 mL inhalation solution, 30 x 2 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2066R NP | ‡1 | 5 | .. | 47.27 | 38.80 | Pulmicort Respules [AP] |

## ▪ CICLESONIDE

**ciclesonide 160 microgram/actuation pressurised inhalation, 120 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8854B NP | ‡1 | 5 | .. | 40.85 | 38.80 | Alvesco 160 [AP] |

**ciclesonide 80 microgram/actuation pressurised inhalation, 120 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8853Y NP | ‡1 | 5 | .. | 27.39 | 28.60 | Alvesco 80 [AP] |

## ▪ FLUTICASONE

**fluticasone propionate 250 microgram/actuation powder for inhalation, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8148W NP | ‡1 | 5 | .. | 27.92 | 29.13 | Flixotide Accuhaler [GK] |

**fluticasone propionate 50 microgram/actuation pressurised inhalation, 120 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8516F NP | ‡1 | 5 | .. | 18.50 | 19.71 | Flixotide Junior [GK] |

**fluticasone propionate 100 microgram/actuation powder for inhalation, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8147T NP | ‡1 | 5 | .. | 18.50 | 19.71 | Flixotide Junior Accuhaler [GK] |

**fluticasone propionate 500 microgram/actuation powder for inhalation, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8149X NP | ‡1 | 1 | .. | 42.06 | 38.80 | Flixotide Accuhaler [GK] |

**fluticasone propionate 125 microgram/actuation pressurised inhalation, 120 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8345F NP | ‡1 | 5 | .. | 27.92 | 29.13 | [a] Flixotide [GK] | [a] Fluticasone Cipla Inhaler [LR] |

**fluticasone propionate 250 microgram/actuation pressurised inhalation, 120 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8346G NP | ‡1 | 1 | .. | 42.06 | 38.80 | [a] Flixotide [GK] | [a] Fluticasone Cipla Inhaler [LR] |

*Anticholinergics*

## ▪ ACLIDINIUM

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**aclidinium 322 microgram/actuation inhalation: powder for, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10124W NP | ‡1 | 5 | .. | 61.97 | 38.80 | Bretaris Genuair [FK] |

## ▪ GLYCOPYRRONIUM

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**glycopyrronium 50 microgram powder for inhalation, 30 capsules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10059K NP | 1 | 5 | .. | 61.97 | 38.80 | seebri breezhaler [NV] |

## ▪ IPRATROPIUM

**ipratropium bromide 20 microgram/actuation inhalation: pressurised, 200 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8671J NP | 2 | 5 | .. | *34.93 | 36.14 | Atrovent [BY] |

## ▪ IPRATROPIUM

**Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

**ipratropium bromide 250 microgram/mL inhalation solution, 30 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1542E NP | 2 | 5 | .. | *27.33 | 28.54 | [a] Aeron 250 [QA]<br>[a] Ipratrin [AF] | [a] APO-Ipratropium [TX] |
| | | | [B]0.50 | *27.83 | 28.54 | [a] Atrovent [BY] | |

**ipratropium bromide 500 microgram/mL inhalation solution, 30 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8238N NP | 2 | 5 | .. | *30.27 | 31.48 | [a] Aeron 500 [QA]<br>[a] Ipratrin Adult [AF] | [a] APO-Ipratropium [TX] |
| | | | [B]0.50 | *30.77 | 31.48 | [a] Atrovent Adult [BY] | |

## ▪ TIOTROPIUM

**Restricted benefit**

Bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease

Treatment Phase: Long-term maintenance treatment

**tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10509D NP | ‡1 | 5 | .. | 59.42 | 38.80 | Spiriva Respimat [BY] |

## ▪ TIOTROPIUM

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**tiotropium 18 microgram powder for inhalation, 30 capsules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8626B NP | 1 | 5 | .. | 59.42 | 38.80 | Spiriva [BY] |

## ▪ TIOTROPIUM

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Restricted benefit**

Severe asthma

**Clinical criteria:**

- Patient must have experienced at least one severe exacerbation, which has required documented use of systemic corticosteroids, in the previous 12 months while receiving optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid and a long acting beta-2 agonist.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

**tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11043F NP | ‡1 | 5 | .. | 59.42 | 38.80 | Spiriva Respimat [BY] |

## ▪ UMECLIDINIUM

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**umeclidinium 62.5 microgram/actuation inhalation: powder for, 30 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10187E NP | ‡1 | 5 | .. | 61.97 | 38.80 | Incruse Ellipta [GK] |

### *Antiallergic agents, excl. corticosteroids*

## ▪ CROMOGLYCATE

**sodium cromoglycate 5 mg/actuation pressurised inhalation, 112 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8334P NP | ‡1 | 5 | .. | 38.82 | 38.80 | Intal Forte CFC-Free [SW] |

**sodium cromoglycate 20 mg powder for inhalation, 100 capsules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2878L NP | 1 | 5 | .. | 32.82 | 34.03 | Intal Spincaps [EA] |

**sodium cromoglycate 1 mg/actuation pressurised inhalation, 200 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8767K NP | ‡1 | 5 | .. | 34.64 | 35.85 | Intal CFC-Free [SW] |

## ▪ NEDOCROMIL

**nedocromil sodium 2 mg/actuation pressurised inhalation, 112 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8365G NP | ‡1 | 5 | .. | 38.72 | 38.80 | Tilade CFC-Free [SW] |

# ADRENERGICS FOR SYSTEMIC USE

### *Alpha- and beta-adrenoreceptor agonists*

## ▪ ADRENALINE

**adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1016L NP | 1 | 1 | .. | 22.58 | 23.79 | Link Medical Products Pty Ltd [LM] |

**adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5004J DP | 1 | .. | .. | 22.58 | 23.79 | Link Medical Products Pty Ltd [LM] |

## ▪ ADRENALINE

**Caution** EpiPen and Anapen products have different administration techniques and should not be prescribed to the same patient without training in their use.

**Note** The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au.)

**Note** Authority approvals will be limited to a maximum quantity of 2 auto-injectors (Anapen or EpiPen) at any one time.

**Note** No applications for repeats will be authorised.

**Authority required**

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.

The name of the specialist consulted must be provided at the time of application for initial supply.

**Authority required**

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have been discharged from hospital or an emergency department after treatment with adrenaline for acute allergic reaction with anaphylaxis.

**Authority required**

Acute allergic reaction with anaphylaxis

Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug.

**adrenaline 300 microgram/0.3 mL injection, 1 dose**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8698T NP | 1 | .. | .. | 97.10 | 38.80 | EpiPen [AL] |

**adrenaline 150 microgram/0.3 mL injection, 1 dose**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8697R NP | 1 | .. | .. | 97.10 | 38.80 | EpiPen Jr. [AL] |

*Selective beta-2-adrenoreceptor agonists*

## ▪ SALBUTAMOL

**salbutamol 2 mg/5 mL oral liquid, 150 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1103C NP | 2 | 5 | .. | *24.81 | 26.02 | Ventolin [GK] |

## ▪ TERBUTALINE

**terbutaline sulfate 500 microgram/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1034K NP | 1 | .. | .. | 31.06 | 32.27 | Bricanyl [AP] |

## OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

*Xanthines*

## ▪ THEOPHYLLINE

**Caution** Because of variable effects of food on absorption of sustained release theophylline preparations, patients stabilised on one brand should not be changed to another without appropriate monitoring.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**theophylline 300 mg modified release tablet, 100**

| 8231F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.94 | 19.15 | Nuelin-SR 300 [IA] |

**theophylline 200 mg modified release tablet, 100**

| 8230E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.83 | 17.04 | Nuelin-SR 200 [IA] |

**theophylline 133.3 mg/25 mL oral liquid, 500 mL**

| 2614N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | .. | 16.68 | 17.89 | Nuelin [IA] |

**theophylline 250 mg modified release tablet, 100**

| 2634P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.79 | 18.00 | Nuelin-SR 250 [IA] |

*Leukotriene receptor antagonists*

## ▪ MONTELUKAST

**Note** This drug is not PBS-subsidised for use in a child aged 2 to 5 years with moderate to severe asthma. It is not intended as an alternative for a child aged 2 to 5 years who requires a corticosteroid as a preventer medication.

**Note** This drug is not subsidised in a child aged 2 to 5 years for use in combination with other preventer medications. PBS subsidy for this drug will therefore cease for a child aged 2 to 5 years who requires a preventer medication in addition to this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***6666***

Asthma

Treatment Phase: First-line prevention

**Population criteria:**

- Patient must be aged 2 to 5 years inclusive.

**Clinical criteria:**

- The condition must be frequent intermittent; OR
- The condition must be mild persistent, **AND**
- The treatment must be the single preventer agent, **AND**
- The treatment must be an alternative to sodium cromoglycate; OR
- The treatment must be an alternative to nedocromil sodium.

**montelukast 4 mg chewable tablet, 28**

| 8627C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 18.24 | 19.45 | [a] APO-Montelukast [TX]<br>[a] Chem mart Montelukast [CH]<br>[a] Montelukast AN [EA]<br>[a] Montelukast Sandoz 4 [SZ]<br>[a] Terry White Chemists Montelukast [TW] | [a] Auro-Montelukast Tabs 4 [DO]<br>[a] Lukair [AL]<br>[a] Montelukast GH [GQ]<br>[a] Respikast 4 [RW] |
| | | | [B]3.00 | 21.24 | 19.45 | [a] Singulair [MK] | |

## ▪ MONTELUKAST

**Note** This drug is not PBS-subsidised for use in a patient aged 15 years or older, or for use in addition to a long-acting beta-agonist in any age group, or for use as a single second line preventer, as an alternative to corticosteroids, in a child aged 6 to 14 years with moderate to severe asthma.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***6674***

Asthma

Treatment Phase: First-line prevention

**Clinical criteria:**

- The condition must be frequent intermittent; OR
- The condition must be mild persistent, **AND**
- The treatment must be the single preventer agent, **AND**
- The treatment must be an alternative to sodium cromoglycate; OR
- The treatment must be an alternative to nedocromil sodium.

**Population criteria:**

- Patient must be aged 6 to 14 years inclusive.

**Authority required (STREAMLINED)**

***6684***

Asthma

Treatment Phase: Prevention of condition

**Clinical criteria:**

- The condition must be exercise-induced, **AND**
- The treatment must be as an alternative to adding salmeterol xinafoate; OR
- The treatment must be as an alternative to adding eformoterol fumarate, **AND**
- The condition must be otherwise well controlled while receiving optimal dose inhaled corticosteroid, **AND**
- Patient must require short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms.

**Population criteria:**

- Patient must be aged 6 to 14 years inclusive.

**montelukast 5 mg chewable tablet, 28**

| 8628D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.82 | 19.03 | [a] APO-Montelukast [TX]<br>[a] Chem mart Montelukast [CH]<br>[a] Montelukast AN [EA]<br>[a] Montelukast Sandoz 5 [SZ]<br>[a] Terry White Chemists Montelukast [TW] | [a] Auro-Montelukast Tabs 5 [DO]<br>[a] Lukair [AL]<br>[a] Montelukast GH [GQ]<br>[a] Respikast 5 [RW] |
| | | | [B]3.00 | 20.82 | 19.03 | [a] Singulair [MK] | |

# COUGH AND COLD PREPARATIONS

## COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS

*Opium alkaloids and derivatives*

### CODEINE

**codeine phosphate 30 mg tablet, 20**

| 1214X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 20.50 | 21.71 | Fawns and McAllan Proprietary Limited [FM] |

# ANTIHISTAMINES FOR SYSTEMIC USE

## ANTIHISTAMINES FOR SYSTEMIC USE

*Phenothiazine derivatives*

### PROMETHAZINE

**promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules**

| 1948M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *38.67 | 38.80 | Hospira Pty Limited [PF] |

# SENSORY ORGANS

# OPHTHALMOLOGICALS

## ANTIINFECTIVES

*Antibiotics*

### AZITHROMYCIN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Trachoma

**azithromycin 200 mg/5 mL powder for oral liquid, 15 mL**

| 8201P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | .. | .. | #26.26 | 27.83 | Zithromax [PF] |

**azithromycin 500 mg tablet, 2**

| 8336R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 15.37 | 16.58 | [a] APO-Azithromycin [TX]<br>[a] Azithromycin Mylan [AF] | [a] Azithromycin-GA [EA]<br>[a] Azithromycin Sandoz [SZ] |

[a] Chem mart Azithromycin [CH] [a] Terry White Chemists Azithromycin [TW]

[a] Zithromax [PF]

## ▪ CHLORAMPHENICOL

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**chloramphenicol 0.5% eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11112W OP NP MW | ‡1 | 2 | .. | 15.07 | 16.28 | Chlorsig [QA] |

## ▪ GENTAMICIN

**Restricted benefit**

Perioperative use in ophthalmic surgery

**Restricted benefit**

Suspected Pseudomonal eye infection

**gentamicin 0.3% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5566Y OP | ‡1 | 2 | .. | 21.41 | 22.62 | Genoptic [AG] |

## ▪ GENTAMICIN

**Restricted benefit**

Invasive ocular infection

**Restricted benefit**

Perioperative use in ophthalmic surgery

**Restricted benefit**

Suspected Pseudomonal eye infection

**gentamicin 0.3% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1441W | ‡1 | 2 | .. | 21.41 | 22.62 | Genoptic [AG] |

## ▪ TOBRAMYCIN

**Restricted benefit**

Perioperative use in ophthalmic surgery

**Restricted benefit**

Suspected Pseudomonal eye infection

**tobramycin 0.3% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5569D OP | ‡1 | 2 | .. | 21.71 | 22.92 | Tobrex [NV] |

**tobramycin 0.3% eye ointment, 3.5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5570E OP | ‡1 | .. | .. | 24.27 | 25.48 | Tobrex [NV] |

## ▪ TOBRAMYCIN

**Restricted benefit**

Invasive ocular infection

**Restricted benefit**

Perioperative use in ophthalmic surgery

**Restricted benefit**

Suspected Pseudomonal eye infection

**tobramycin 0.3% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2328M | ‡1 | 2 | .. | 21.71 | 22.92 | Tobrex [NV] |

**tobramycin 0.3% eye ointment, 3.5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2329N | ‡1 | .. | .. | 24.27 | 25.48 | Tobrex [NV] |

*Antivirals*

## ▪ ACICLOVIR

**Restricted benefit**

Herpes simplex keratitis

**aciclovir 3% eye ointment, 4.5 g**

| 5501M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| OP | ‡1 | .. | .. | 38.08 | 38.80 | Zovirax [GK] |

## ▪ ACICLOVIR

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Herpes simplex keratitis

**aciclovir 3% eye ointment, 4.5 g**

| 1002R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | .. | .. | 38.08 | 38.80 | Zovirax [GK] |

*Fluoroquinolones*

## ▪ CIPROFLOXACIN

**Authority required**

Bacterial keratitis

**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**ciprofloxacin 0.3% eye drops, 5 mL**

| 1217C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *30.27 | 31.48 | [a] CiloQuin [NM] |
| | | | [B]4.36 | *34.63 | 31.48 | [a] Ciloxan [NV] |

## ▪ CIPROFLOXACIN

**Authority required**

Bacterial keratitis

**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**ciprofloxacin 0.3% eye drops, 5 mL**

| 5564W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| OP | 2 | .. | .. | *30.27 | 31.48 | [a] CiloQuin [NM] |
| | | | [B]4.36 | *34.63 | 31.48 | [a] Ciloxan [NV] |

## ▪ OFLOXACIN

**Authority required**

Bacterial keratitis

**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**ofloxacin 0.3% eye drops, 5 mL**

| 5567B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| OP | 2 | .. | .. | *34.95 | 36.16 | Ocuflox [AG] |

## ▪ OFLOXACIN

**Authority required**

Bacterial keratitis

**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**ofloxacin 0.3% eye drops, 5 mL**

| 8383F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *34.95 | 36.16 | Ocuflox [AG] |

# ANTIINFLAMMATORY AGENTS

*Corticosteroids, plain*

## ▪ DEXAMETHASONE

### DEXAMETHASONE Eye drops 1 mg per mL (0.1%), 5 mL, 1

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1288T NP | ‡1 | 2 | .. | 14.73 | 15.94 | Maxidex [NV] |

## ▪ DEXAMETHASONE

**Note** No applications for increased maximum quantities will be authorised.
**Note** No applications for increased repeats will be authorised.

### DEXAMETHASONE Eye drops 1 mg per mL (0.1%), 5 mL, 1

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5565X OP | ‡1 | .. | .. | 14.73 | 15.94 | Maxidex [NV] |

## ▪ DEXAMETHASONE

**Note** Special Pricing Arrangements apply.

**Authority required**

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; OR
- Patient must be unsuitable for treatment with VEGF inhibitors; OR
- Patient must have failed prior treatment with VEGF inhibitors, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Population criteria:**

- Patient must have had a cataract removed in the treated eye; OR
- Patient must be scheduled for cataract surgery in the treated eye.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

a) a completed authority prescription form;

b) a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and

c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Authority required**

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Population criteria:**

- Patient must have had a cataract removed in the treated eye; OR
- Patient must be scheduled for cataract surgery in the treated eye.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Diabetic macular oedema (DMO)

Treatment Phase: Grandfathering treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 November 2016, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Population criteria:**

- Patient must have had a cataract removed in the treated eye; OR
- Patient must be scheduled for cataract surgery in the treated eye.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

a) a completed authority prescription form;

b) a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and

c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**dexamethasone 700 microgram implant, 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10943Y | 1 | 1 | .. | 1354.79 | 38.80 | Ozurdex [AG] |

## ▪ FLUOROMETHOLONE

**fluorometholone 0.1% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1204J NP | ‡1 | 5 | .. | 14.55 | 15.76 | Flucon [NV] | FML Liquifilm [AG] |

## ▪ FLUOROMETHOLONE

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will be authorised.

**fluorometholone 0.1% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5513E OP | ‡1 | .. | .. | 14.55 | 15.76 | Flucon [NV] | FML Liquifilm [AG] |

## ▪ FLUOROMETHOLONE ACETATE

**fluorometholone acetate 0.1% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1438Q NP | ‡1 | 2 | .. | 14.55 | 15.76 | Flarex [NV] |

## ▪ FLUOROMETHOLONE ACETATE

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will be authorised.

**fluorometholone acetate 0.1% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5533F OP | ‡1 | .. | .. | 14.55 | 15.76 | Flarex [NV] |

## ▪ HYDROCORTISONE ACETATE

**hydrocortisone acetate 1% eye ointment, 5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2441L NP | ‡1 | .. | .. | 16.54 | 17.75 | Hycor [QA] |

## ▪ HYDROCORTISONE ACETATE

**Note** No applications for increased maximum quantities will be authorised.
**Note** No applications for increased repeats will be authorised.

**hydrocortisone acetate 1% eye ointment, 5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5516H OP | ‡1 | .. | .. | 16.54 | 17.75 | Hycor [QA] |

*Corticosteroids and mydriatics in combination*

## ▪ PREDNISOLONE ACETATE + PHENYLEPHRINE

**Restricted benefit**
Corneal grafts
**Restricted benefit**
Uveitis

**prednisolone acetate 1% + phenylephrine hydrochloride 0.12% eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3112T NP | ‡1 | 2 | .. | 27.96 | 29.17 | Prednefrin Forte [AG] |

## ▪ PREDNISOLONE ACETATE + PHENYLEPHRINE

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**
Uveitis

**prednisolone acetate 1% + phenylephrine hydrochloride 0.12% eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5568C OP | ‡1 | .. | .. | 27.96 | 29.17 | Prednefrin Forte [AG] |

# ANTIGLAUCOMA PREPARATIONS AND MIOTICS

*Sympathomimetics in glaucoma therapy1)*

## ▪ APRACLONIDINE

**Restricted benefit**
Intra-ocular pressure
**Clinical criteria:**

- The treatment must be for short-term reduction of intra-ocular pressure, **AND**
- Patient must already be on maximally tolerated anti-glaucoma therapy.

**apraclonidine 0.5% eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8083K | ‡1 | 2 | .. | 40.40 | 38.80 | Iopidine 0.5% [NV] |

## ▪ BRIMONIDINE

**brimonidine tartrate 0.15% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5298W | ‡1 | 5 | .. | 23.02 | 24.23 | Alphagan P 1.5 [AG] |

**brimonidine tartrate 0.2% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8351M | ‡1 | 5 | .. | 23.02 | 24.23 | [a] Enidin [PE] |
| | | | [B]1.42 | 24.44 | 24.23 | [a] Alphagan [AG] |

## ▪ BRIMONIDINE

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**brimonidine tartrate 0.15% eye drops, 5 mL**

| 5563T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| OP | ‡1 | 5 | .. | 23.02 | 24.23 | Alphagan P 1.5 [AG] |

**brimonidine tartrate 0.2% eye drops, 5 mL**

| 5534G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| OP | ‡1 | 5 | .. | 23.02 | 24.23 | [a] Enidin [PE] |
| | | | [B]1.42 | 24.44 | 24.23 | [a] Alphagan [AG] |

## ▪ BRIMONIDINE + TIMOLOL

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL**

| 8826M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 5 | .. | 28.14 | 29.35 | Combigan [AG] |

## ▪ BRIMONIDINE + TIMOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL**

| 5535H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| OP | ‡1 | 5 | .. | 28.14 | 29.35 | Combigan [AG] |

*Parasympathomimetics*

## ▪ PILOCARPINE

**pilocarpine hydrochloride 4% eye drops, 15 mL**

| 2598R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 5 | .. | 19.97 | 21.18 | Isopto Carpine [NV] |

**pilocarpine hydrochloride 1% eye drops, 15 mL**

| 2595N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 5 | .. | 16.40 | 17.61 | Isopto Carpine [NV] |

**pilocarpine hydrochloride 2% eye drops, 15 mL**

| 2596P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 5 | .. | 17.49 | 18.70 | Isopto Carpine [NV] |

## ▪ PILOCARPINE

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**pilocarpine hydrochloride 4% eye drops, 15 mL**

| 5538L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| OP | ‡1 | 5 | .. | 19.97 | 21.18 | Isopto Carpine [NV] |

**pilocarpine hydrochloride 1% eye drops, 15 mL**

| 5536J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| OP | ‡1 | 5 | .. | 16.40 | 17.61 | Isopto Carpine [NV] |

**pilocarpine hydrochloride 2% eye drops, 15 mL**

| 5537K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| OP | ‡1 | 5 | .. | 17.49 | 18.70 | Isopto Carpine [NV] |

*Carbonic anhydrase inhibitors*

## ▪ ACETAZOLAMIDE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**acetazolamide 250 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1004W NP | 1 | 3 | .. | 26.91 | 28.12 | Diamox [RW] |

## ▪ BRINZOLAMIDE

**brinzolamide 1% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8483L | ‡1 | 5 | .. | 25.31 | 26.52 | [a] BrinzoQuin [NM] |
| | | | [B]4.78 | 30.09 | 26.52 | [a] Azopt [NV] |

## ▪ BRINZOLAMIDE

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**brinzolamide 1% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5540N OP | ‡1 | 5 | .. | 25.31 | 26.52 | [a] BrinzoQuin [NM] |
| | | | [B]4.78 | 30.09 | 26.52 | [a] Azopt [NV] |

## ▪ BRINZOLAMIDE + BRIMONIDINE

**Restricted benefit**
Elevated intra-ocular pressure
**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10536M | ‡1 | 5 | .. | 27.65 | 28.86 | Simbrinza 1%/0.2% [NV] |

## ▪ BRINZOLAMIDE + BRIMONIDINE

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**
Elevated intra-ocular pressure
**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10547D OP | ‡1 | 5 | .. | 27.65 | 28.86 | Simbrinza 1%/0.2% [NV] |

## ▪ BRINZOLAMIDE + TIMOLOL

**Restricted benefit**
Elevated intra-ocular pressure
**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**brinzolamide 1% + timolol 0.5% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3438Y | ‡1 | 5 | .. | 28.88 | 30.09 | Azarga [NV] |

## ▪ BRINZOLAMIDE + TIMOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**
Elevated intra-ocular pressure
**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**brinzolamide 1% + timolol 0.5% eye drops, 5 mL**

5562R (OP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 28.88 | 30.09 | Azarga [NV] |

## ▪ DORZOLAMIDE

**dorzolamide 2% eye drops, 5 mL**

8488R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 5 | .. | 21.96 | 23.17 | [a] Trusamide [QA] | [a] Trusopt [MF] |

## ▪ DORZOLAMIDE

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**dorzolamide 2% eye drops, 5 mL**

5541P (OP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 5 | .. | 21.96 | 23.17 | [a] Trusamide [QA] | [a] Trusopt [MF] |

## ▪ DORZOLAMIDE + TIMOLOL

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**dorzolamide 2% + timolol 0.5% eye drops, 5 mL**

8567X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 5 | .. | 24.08 | 25.29 | [a] Cosdor [QA] | [a] DORZOLAMIDE/TIMOLOL AN 20/5 [EA] |
| | | | | | [a] Dorzolamide/Timolol Sandoz 20/5 [SZ] | |
| | | [B]1.00 | 25.08 | 25.29 | [a] Cosopt [MF] | |

## ▪ DORZOLAMIDE + TIMOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**dorzolamide 2% + timolol 0.5% eye drops, 5 mL**

5542Q (OP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 5 | .. | 24.08 | 25.29 | [a] Cosdor [QA] | [a] DORZOLAMIDE/TIMOLOL AN 20/5 [EA] |
| | | | | | [a] Dorzolamide/Timolol Sandoz 20/5 [SZ] | |
| | | [B]1.00 | 25.08 | 25.29 | [a] Cosopt [MF] | |

*Beta blocking agents1)*

## ▪ BETAXOLOL

**betaxolol 0.5% eye drops, 5 mL**

2825Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 18.35 | 19.56 | [a] BetoQuin [NM] |
| | | [B]4.76 | 23.11 | 19.56 | [a] Betoptic [NV] |

**betaxolol 0.25% eye drops, 5 mL**

2811Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 18.35 | 19.56 | Betoptic S [NV] |

## ▪ BETAXOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**betaxolol 0.5% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5544T OP | ‡1 | 5 | .. | 18.35 | 19.56 | [a] BetoQuin [NM] |
| | | | [B]4.76 | 23.11 | 19.56 | [a] Betoptic [NV] |

**betaxolol 0.25% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5543R OP | ‡1 | 5 | .. | 18.35 | 19.56 | Betoptic S [NV] |

## ▪ TIMOLOL

**timolol 0.5% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1279H | ‡1 | 5 | .. | 16.21 | 17.42 | Timoptol [MF] |

**timolol 0.1% eye gel, 5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8803H | ‡1 | 5 | .. | 16.70 | 17.91 | Nyogel [AS] |

**timolol 0.5% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1926J | ‡1 | 5 | .. | 16.21 | 17.42 | Timoptol XE [MF] |

**timolol 0.25% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1925H | ‡1 | 5 | .. | 15.54 | 16.75 | Timoptol XE [MF] |

## ▪ TIMOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**timolol 0.5% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5548B OP | ‡1 | 5 | .. | 16.21 | 17.42 | Timoptol [MF] |

**timolol 0.1% eye gel, 5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5546X OP | ‡1 | 5 | .. | 16.70 | 17.91 | Nyogel [AS] |

**timolol 0.5% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5550D OP | ‡1 | 5 | .. | 16.21 | 17.42 | Timoptol XE [MF] |

**timolol 0.25% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5549C OP | ‡1 | 5 | .. | 15.54 | 16.75 | Timoptol XE [MF] |

*Prostaglandin analogues1)*

## ▪ BIMATOPROST

**bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10046R | ‡1 | 5 | .. | 32.01 | 33.22 | Lumigan PF [AG] |

**bimatoprost 0.03% eye drops, 3 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8620Q | ‡1 | 5 | .. | 36.01 | 37.22 | [a] Bimatoprost Sandoz [SZ] | [a] Lumigan [AG] |

## ▪ BIMATOPROST

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10053D OP | ‡1 | 5 | .. | 32.01 | 33.22 | Lumigan PF [AG] |

**bimatoprost 0.03% eye drops, 3 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5551E OP | ‡1 | 5 | .. | 36.01 | 37.22 | [a] Bimatoprost Sandoz [SZ] | [a] Lumigan [AG] |

## ▪ BIMATOPROST + TIMOLOL

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10107Y | ‡1 | 5 | .. | 35.74 | 36.95 | GANfort PF 0.3/5 [AG] |

## ▪ BIMATOPROST + TIMOLOL

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9464D | ‡1 | 5 | .. | 40.46 | 38.80 | Ganfort 0.3/5 [AG] |

## ▪ BIMATOPROST + TIMOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5558M OP | ‡1 | 5 | .. | 40.46 | 38.80 | Ganfort 0.3/5 [AG] |

**bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10108B OP | ‡1 | 5 | .. | 35.74 | 36.95 | GANfort PF 0.3/5 [AG] |

## ▪ LATANOPROST

**latanoprost 0.005% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8243W | ‡1 | 5 | .. | 16.92 | 18.13 | [a] APO-Latanoprost [TX]<br>[a] Lanpro [JU]<br>[a] Latanoprost GH [GQ]<br>[a] Terry White Chemists Latanoprost [TW]<br>[a] Xalatan [PF] | [a] Chem mart Latanoprost [CH]<br>[a] Latanoprost Actavis [EA]<br>[a] Latanoprost Sandoz [SZ]<br>[a] Xalaprost [QA] |

## ▪ LATANOPROST

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**latanoprost 0.005% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5552F OP | ‡1 | 5 | .. | 16.92 | 18.13 | [a] APO-Latanoprost [TX]<br>[a] Lanpro [JU]<br>[a] Latanoprost GH [GQ]<br>[a] Terry White Chemists Latanoprost [TW]<br>[a] Xalatan [PF] | [a] Chem mart Latanoprost [CH]<br>[a] Latanoprost Actavis [EA]<br>[a] Latanoprost Sandoz [SZ]<br>[a] Xalaprost [QA] |

## ▪ LATANOPROST + TIMOLOL

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL**

8895E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 5 | .. | 21.37 | 22.58 | [a] APO-Latanoprost/Timolol 0.05/5 [TX] | [a] Lantim [JU] |
| | | | | | [a] Latanoprost/timolol AN 50/5 [EA] | [a] Latanoprost/Timolol Sandoz 50/5 [SZ] |
| | | | | | [a] Xalacom [PF] | [a] Xalamol 50/5 [QA] |

## ▪ LATANOPROST + TIMOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL**

5553G

OP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 5 | .. | 21.37 | 22.58 | [a] APO-Latanoprost/Timolol 0.05/5 [TX] | [a] Lantim [JU] |
| | | | | | [a] Latanoprost/timolol AN 50/5 [EA] | [a] Latanoprost/Timolol Sandoz 50/5 [SZ] |
| | | | | | [a] Xalacom [PF] | [a] Xalamol 50/5 [QA] |

## ▪ TAFLUPROST

**tafluprost 0.0015% eye drops, 30 x 0.3 mL unit doses**

2755B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 34.92 | 36.13 | Saflutan [MF] |

## ▪ TAFLUPROST

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**tafluprost 0.0015% eye drops, 30 x 0.3 mL unit doses**

2748P

OP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 34.92 | 36.13 | Saflutan [MF] |

## ▪ TRAVOPROST

**travoprost 0.004% eye drops, 2.5 mL**

8597L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 40.75 | 38.80 | Travatan [NV] |

## ▪ TRAVOPROST

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**travoprost 0.004% eye drops, 2.5 mL**

5554H

OP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 40.75 | 38.80 | Travatan [NV] |

## ▪ TRAVOPROST + TIMOLOL

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**travoprost 0.004% + timolol 0.5% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9057Q | ‡1 | 5 | .. | 45.21 | 38.80 | Duotrav [NV] |

## ▪ TRAVOPROST + TIMOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**travoprost 0.004% + timolol 0.5% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5555J OP | ‡1 | 5 | .. | 45.21 | 38.80 | Duotrav [NV] |

# MYDRIATICS AND CYCLOPLEGICS

*Anticholinergics*

## ▪ ATROPINE SULFATE

**ATROPINE Eye drops containing atropine sulfate 10 mg per mL (1%), 15 mL, 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1093M NP | ‡1 | 2 | .. | 23.78 | 24.99 | Atropt [QA] |

# DECONGESTANTS AND ANTIALLERGICS

*Other antiallergics*

## ▪ CROMOGLYCATE

**Restricted benefit**

Vernal kerato-conjunctivitis

**sodium cromoglycate 2% eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1127H NP | ‡1 | 5 | .. | 17.86 | 19.07 | Opticrom [SW] |

**sodium cromoglycate 2% eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5529B OP | ‡1 | 5 | .. | 17.86 | 19.07 | Opticrom [SW] |

# OCULAR VASCULAR DISORDER AGENTS

*Antineovascularisation agents*

## ▪ AFLIBERCEPT

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

a) a completed authority prescription form;

b) a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and

c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Authority required**

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### aflibercept 4 mg/0.1 mL injection, 0.1 mL vial

10505X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1149.44 | 38.80 | Eylea [BN] |

## ▪ AFLIBERCEPT

**Note** Special Pricing Arrangements apply.

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

a) a completed authority prescription form;

b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and

c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been granted an authority prescription for the same eye.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Note** Authority approvals will be administered by the Complex Drugs Unit of the Department of Human Services.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Branch retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

a) a completed authority prescription form;

b) a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and

c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Branch retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Central retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**

- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

a) a completed authority prescription form;

b) a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and

c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**aflibercept 4 mg/0.1 mL injection, 0.1 mL vial**

2168D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 1149.44 | 38.80 | Eylea [BN] |

## ▪ RANIBIZUMAB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Authority required**

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

a) a completed authority prescription form;

b) a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and

c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Authority required**

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**ranibizumab 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe**

10374B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1149.44 | 38.80 | [a] Lucentis [NV] |

**ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial**

10373Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1149.44 | 38.80 | [a] Lucentis [NV] |

## ▪ RANIBIZUMAB

**Note** Special Pricing Arrangements apply.

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

a) a completed authority prescription form;

b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and

c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been granted an authority prescription for the same eye.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Branch retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

a) a completed authority prescription form;

b) a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and

c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Branch retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Central retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

a) a completed authority prescription form;

b) a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and

c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### ranibizumab 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe

10138N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 1149.44 | 38.80 | [a] Lucentis [NV] |

## ▪ RANIBIZUMAB

**Note** Special Pricing Arrangements apply.

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

a) a completed authority prescription form;

b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and

c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been granted an authority prescription for the same eye.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Branch retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

a) a completed authority prescription form;

b) a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and

c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Branch retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Central retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

a) a completed authority prescription form;

b) a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and

c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial

1382R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 1149.44 | 38.80 | [a] Lucentis [NV] |

## ▪ VERTEPORFIN

**Note** The Department of Human Services should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum.

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be predominantly classic (greater than or equal to 50%).

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by fluorescein angiography, **AND**
- Patient must have a baseline visual acuity equal to or better than 6/60 (20/200).

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

a) a completed authority prescription form;

b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and

c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the fluorescein angiogram.

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note** No more than 15 treatments (1 initial and 14 continuing) per eye will be authorised.

**Note** Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial PBS-subsidised treatment

**Clinical criteria:**

- The condition must be predominantly classic (greater than or equal to 50%), **AND**
- The condition must be due to macular degeneration, **AND**
- Patient must have been authorised by the Angiogram Review Panel to receive treatment with verteporfin in the same eye under the MBS Visudyne Therapy Program, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a ophthalmologist.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

(a) a completed authority prescription form; and

(b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form, which includes the date of review by the Angiogram Review Panel and the number of treatments administered in that eye under the MBS Visudyne Therapy Program; and

(c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the fluorescein angiogram.

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note** A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS.

**Note** Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be predominantly classic (greater than or equal to 50%), **AND**
- The condition must be due to macular degeneration, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been granted an authority prescription for the same eye.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Note** A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**verteporfin 15 mg injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1349B | 1 | .. | .. | 2142.00 | 38.80 | Visudyne [NV] |

## OTHER OPHTHALMOLOGICALS

*Other ophthalmologicals*

### ▪ CARBOMER-974

**Authority required (STREAMLINED)**

***6172***

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**carbomer-974 0.3% eye gel, 30 x 500 mg unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5502N OP | 3 | 5 | .. | *35.56 | 36.77 | Poly Gel [NV] |

**carbomer-974 0.3% eye gel, 30 x 500 mg unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8514D NP | 3 | 5 | .. | *35.56 | 36.77 | Poly Gel [NV] |

### ▪ CARBOMER-980

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**carbomer-980 0.2% eye gel, 10 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5503P OP | ‡1 | 5 | .. | 13.91 | 15.12 | [a] Optifresh eye gel [PP] | [a] PAA [IA] |
| | | | [B]3.85 | 17.76 | 15.12 | [a] Viscotears [IV] | |

**carbomer-980 0.2% eye gel, 10 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8384G NP | ‡1 | 5 | .. | 13.91 | 15.12 | [a] Optifresh eye gel [PP] | [a] PAA [IA] |
| | | | [B]3.85 | 17.76 | 15.12 | [a] Viscotears [IV] | |

### ▪ CARBOMER-980

**Authority required (STREAMLINED)**

***6172***

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**carbomer-980 0.2% eye drops, 30 x 0.6 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5504Q OP | 3 | 5 | .. | *36.88 | 38.09 | Viscotears Gel PF [IV] |

**carbomer-980 0.2% eye drops, 30 x 0.6 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8578L NP | 3 | 5 | .. | *36.88 | 38.09 | Viscotears Gel PF [IV] |

### ▪ CARBOMER-980

**Note** No applications for increased maximum quantities will be authorised.
**Note** No applications for repeats will be authorised.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**carbomer-980 0.2% eye gel, 10 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9210R | ‡1 | 11 | .. | 13.91 | 15.12 | [a] Optifresh eye gel [PP] | [a] PAA [IA] |
| | | | [B]3.85 | 17.76 | 15.12 | [a] Viscotears [IV] | |

### ▪ CARMELLOSE SODIUM

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**carmellose sodium 0.5% (5 mg/mL) eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5507W OP | ‡1 | 5 | .. | 14.54 | 15.75 | Refresh Tears Plus [AG] |

**carmellose sodium 1% (10 mg/mL) eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5508X OP | ‡1 | 5 | .. | 14.54 | 15.75 | Refresh Liquigel [AG] |

## ▪ CARMELLOSE SODIUM

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**carmellose sodium 0.5% (5 mg/mL) eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8548X NP | ‡1 | 5 | .. | 14.54 | 15.75 | Refresh Tears Plus [AG] |

**carmellose sodium 1% (10 mg/mL) eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8593G NP | ‡1 | 5 | .. | 14.54 | 15.75 | Refresh Liquigel [AG] |

## ▪ CARMELLOSE SODIUM

**Authority required (STREAMLINED)**

***6172***

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2324H NP | 3 | 5 | .. | *31.63 | 32.84 | [a] Optifresh Plus [PP] |
| | | | [B]7.29 | *38.92 | 32.84 | [a] Celluvisc [AG] |

**carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5505R OP | 3 | 5 | .. | *31.63 | 32.84 | [a] Optifresh Plus [PP] |
| | | | [B]7.29 | *38.92 | 32.84 | [a] Celluvisc [AG] |

**carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5509Y OP | 4 | 5 | .. | *39.19 | 38.80 | TheraTears [CX] |

**carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8823J NP | 4 | 5 | .. | *39.19 | 38.80 | TheraTears [CX] |

**carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2338C NP | 3 | 5 | .. | *31.63 | 32.84 | [a] Optifresh Tears [PP] |
| | | | [B]7.29 | *38.92 | 32.84 | [a] Cellufresh [AG] |

**carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5506T OP | 3 | 5 | .. | *31.63 | 32.84 | [a] Optifresh Tears [PP] |
| | | | [B]7.29 | *38.92 | 32.84 | [a] Cellufresh [AG] |

**carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5510B OP | 3 | 5 | .. | *33.94 | 35.15 | TheraTears [CX] |

**carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8824K NP | 3 | 5 | .. | *33.94 | 35.15 | TheraTears [CX] |

## ▪ CARMELLOSE SODIUM

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**carmellose sodium 0.5% (5 mg/mL) eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9211T | ‡1 | 11 | .. | 14.54 | 15.75 | Refresh Tears Plus [AG] |

**carmellose sodium 1% (10 mg/mL) eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9212W | ‡1 | 11 | .. | 14.54 | 15.75 | Refresh Liquigel [AG] |

## ▪ CARMELLOSE SODIUM + GLYCEROL

**Note** The in-use shelf life of Optive is 6 months from the date of opening.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5556K OP | ‡1 | 3 | .. | 14.54 | 15.75 | Optive [AG] |

## ▪ CARMELLOSE SODIUM + GLYCEROL

**Note** The in-use shelf life of Optive is 6 months from the date of opening.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9355J NP | ‡1 | 3 | .. | 14.54 | 15.75 | Optive [AG] |

## ▪ CARMELLOSE SODIUM + GLYCEROL

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The in-use shelf life of Optive is 6 months from the date of opening.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9356K | ‡1 | 7 | .. | 14.54 | 15.75 | Optive [AG] |

## ▪ DEXTRAN-70 + HYPROMELLOSE

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1509K NP | ‡1 | 5 | .. | 14.63 | 15.84 | [a] Poly-Tears [NM] |
| | | | [B]3.65 | 18.28 | 15.84 | [a] Tears Naturale [NV] |

## ▪ DEXTRAN-70 + HYPROMELLOSE

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5520M OP | ‡1 | 5 | .. | 14.63 | 15.84 | [a] Poly-Tears [NM] |
| | | | [B]3.65 | 18.28 | 15.84 | [a] Tears Naturale [NV] |

## ▪ DEXTRAN-70 + HYPROMELLOSE

**Authority required (STREAMLINED)**

***6172***
Severe dry eye syndrome
**Clinical criteria:**
- Patient must be sensitive to preservatives in multi-dose eye drops.

**dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses**

5521N (OP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *35.98 | 37.19 | Bion Tears [NV] |

**dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses**

8299T (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *35.98 | 37.19 | Bion Tears [NV] |

## ▪ DEXTRAN-70 + HYPROMELLOSE

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**
Severe dry eye syndrome, including Sjogren's syndrome
**Clinical criteria:**
- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL**

9216C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 11 | .. | 14.63 | 15.84 | [a] Poly-Tears [NM] |
| | | [B]3.65 | 18.28 | 15.84 | [a] Tears Naturale [NV] |

## ▪ HYPROMELLOSE

**Restricted benefit**
Severe dry eye syndrome, including Sjogren's syndrome

**HYPROMELLOSE Eye drops 5 mg per mL (0.5%), 15 mL, 1**

2956N (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 14.44 | 15.65 | Methopt [QA] |

**HYPROMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1**

8287E (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 14.44 | 15.65 | [a] In a Wink Moisturising [NM] |
| | | [B]4.00 | 18.44 | 15.65 | [a] Genteal [NV] |

## ▪ HYPROMELLOSE

**Restricted benefit**
Severe dry eye syndrome, including Sjogren's syndrome

**HYPROMELLOSE Eye drops 5 mg per mL (0.5%), 15 mL, 1**

5517J (OP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 14.44 | 15.65 | Methopt [QA] |

**HYPROMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1**

5518K (OP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 14.44 | 15.65 | [a] In a Wink Moisturising [NM] |
| | | [B]4.00 | 18.44 | 15.65 | [a] Genteal [NV] |

## ▪ HYPROMELLOSE

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**
Severe dry eye syndrome, including Sjogren's syndrome
**Clinical criteria:**
- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**HYPROMELLOSE Eye drops 5 mg per mL (0.5%), 15 mL, 1**

9214Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 11 | .. | 14.44 | 15.65 | Methopt [QA] |

**HYPROMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9213X | ‡1 | 11 | .. | 14.44 | 15.65 | [a] In a Wink Moisturising [NM] |
| | | | [B]4.00 | 18.44 | 15.65 | [a] Genteal [NV] |

## ▪ HYPROMELLOSE + CARBOMER-980

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5519L OP | ‡1 | 5 | .. | 14.44 | 15.65 | [a] HPMC PAA [NM] |
| | | | [B]4.00 | 18.44 | 15.65 | [a] Genteal gel [NV] |

## ▪ HYPROMELLOSE + CARBOMER-980

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8564R NP | ‡1 | 5 | .. | 14.44 | 15.65 | [a] HPMC PAA [NM] |
| | | | [B]4.00 | 18.44 | 15.65 | [a] Genteal gel [NV] |

## ▪ HYPROMELLOSE + CARBOMER-980

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9215B | ‡1 | 11 | .. | 14.44 | 15.65 | [a] HPMC PAA [NM] |
| | | | [B]4.00 | 18.44 | 15.65 | [a] Genteal gel [NV] |

## ▪ OCRIPLASMIN

**Note** Where authority approval for treatment for both eyes simultaneously is being sought, a maximum quantity of 2 vials may be requested.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Vitreomacular traction syndrome

**Clinical criteria:**

- Patient must have visual impairment due to vitreomacular traction (VMT) without a full thickness macular hole (FTMH); OR
- Patient must have visual impairment due to vitreomacular traction (VMT) with a full thickness macular hole (FTMH) of a diameter of less than or equal to 400 micrometres, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score of approximate Snellen equivalent 20/25 or worse in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography, **AND**
- The condition must have a vitreomacular adhesion diameter less than or equal to 1500 micrometres, **AND**
- Patient must not have an epiretinal membrane attached to the vitreomacular traction, **AND**
- The condition must be previously untreated in the eye proposed for treatment, **AND**
- Patient must not have received prior vitrectomy in the eye proposed for treatment, **AND**
- Patient must be symptomatic.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

The prescriber must state which eye(s) is being treated at the time of application.

**ocriplasmin 500 microgram/0.2 mL injection, 0.2 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10947E | 1 | .. | .. | 4149.52 | 38.80 | Jetrea [NV] |

## ▪ PARAFFIN

**paraffin 1 g/g eye ointment, 3.5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1754H NP | 2 | 5 | .. | *23.97 | 25.18 | Poly Visc [NV] |

**paraffin 1 g/g eye ointment, 3.5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5523Q OP | 2 | 5 | .. | *23.97 | 25.18 | Poly Visc [NV] |

**paraffin 1 g/g eye ointment, 2 x 3.5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1750D NP | ‡1 | 5 | .. | 23.42 | 24.63 | Poly Visc [NV] |
| | | | | | | [a] Ircal [PE] |
| | | | [B]1.84 | 25.26 | 24.63 | [a] Refresh Night Time [AG] |

**paraffin 1 g/g eye ointment, 2 x 3.5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5522P OP | ‡1 | 5 | .. | 23.42 | 24.63 | Poly Visc [NV] |
| | | | | | | [a] Ircal [PE] |
| | | | [B]1.84 | 25.26 | 24.63 | [a] Refresh Night Time [AG] |

## ▪ PARAFFIN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**paraffin 1 g/g eye ointment, 2 x 3.5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9218E | ‡1 | 11 | .. | 23.42 | 24.63 | Poly Visc [NV] |
| | | | | | | [a] Ircal [PE] |
| | | | [B]1.84 | 25.26 | 24.63 | [a] Refresh Night Time [AG] |

## ▪ PARAFFIN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**paraffin 1 g/g eye ointment, 3.5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9217D | 2 | 11 | .. | *23.97 | 25.18 | Poly Visc [NV] |

## ▪ PARAFFIN

**Note** The in-use shelf life of VitA-POS is 6 months from the date of opening.

**paraffin + retinol palmitate 0.0138% eye ointment, 5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2167C OP | 2 | 5 | .. | *23.97 | 25.18 | VitA-POS [AE] |

**paraffin + retinol palmitate 0.0138% eye ointment, 5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2222Y NP | 2 | 5 | .. | *23.97 | 25.18 | VitA-POS [AE] |

## ▪ PARAFFIN

**Note** The in-use shelf life of VitA-POS is 6 months from the date of opening.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**paraffin + retinol palmitate 0.0138% eye ointment, 5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2202X | 2 | 11 | .. | *23.97 | 25.18 | VitA-POS [AE] |

## ▪ POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5524R OP | ‡1 | 5 | .. | 14.54 | 15.75 | Systane [NV] |

## ▪ POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8676P NP | ‡1 | 5 | .. | 14.54 | 15.75 | Systane [NV] |

## ▪ POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

**Authority required (STREAMLINED)**

***6172***

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5532E OP | 2 | 5 | .. | *33.95 | 35.16 | Systane [NV] |

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9170P NP | 2 | 5 | .. | *33.95 | 35.16 | Systane [NV] |

## ▪ POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9219F | ‡1 | 11 | .. | 14.54 | 15.75 | Systane [NV] |

## ▪ POLYVINYL ALCOHOL

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**polyvinyl alcohol 3% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8832W NP | ‡1 | 5 | .. | 14.44 | 15.65 | Vistil Forte [AE] |

**polyvinyl alcohol 1.4% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2682E NP | ‡1 | 5 | .. | 14.44 | 15.65 | [a] PVA Tears [PE] |
| | | | [B]1.39 | 15.83 | 15.65 | [a] Liquifilm Tears [AG] |

**polyvinyl alcohol 1.4% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8831T NP | ‡1 | 5 | .. | 14.44 | 15.65 | Vistil [AE] |

## ▪ POLYVINYL ALCOHOL

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**polyvinyl alcohol 3% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5528Y OP | ‡1 | 5 | .. | 14.44 | 15.65 | Vistil Forte [AE] |

**polyvinyl alcohol 1.4% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5526W OP | ‡1 | 5 | .. | 14.44 | 15.65 | [a] PVA Tears [PE] |
| | | | [B]1.39 | 15.83 | 15.65 | [a] Liquifilm Tears [AG] |

**polyvinyl alcohol 1.4% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5527X OP | ‡1 | 5 | .. | 14.44 | 15.65 | Vistil [AE] |

## ▪ POLYVINYL ALCOHOL

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**polyvinyl alcohol 3% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9223K | ‡1 | 11 | .. | 14.44 | 15.65 | Vistil Forte [AE] |

**polyvinyl alcohol 1.4% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9220G | ‡1 | 11 | .. | 14.44 | 15.65 | [a] PVA Tears [PE] |
| | | | [B]1.39 | 15.83 | 15.65 | [a] Liquifilm Tears [AG] |

**polyvinyl alcohol 1.4% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9221H | ‡1 | 11 | .. | 14.44 | 15.65 | Vistil [AE] |

## ▪ SODIUM HYALURONATE

**Note** The in-use shelf life of Hylo-Fresh and Hylo-Forte is 6 months from the date of opening.

**Authority required (STREAMLINED)**

***4105***

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**sodium hyaluronate 0.1% (1 mg/mL) eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2181T NP | ‡1 | 5 | .. | 34.74 | 35.95 | Hylo-Fresh [AE] |

**sodium hyaluronate 0.1% (1 mg/mL) eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2184Y OP | ‡1 | 5 | .. | 34.74 | 35.95 | Hylo-Fresh [AE] |

**sodium hyaluronate 0.2% (2 mg/mL) eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2171G OP | ‡1 | 5 | .. | 34.74 | 35.95 | Hylo-Forte [AE] |

**sodium hyaluronate 0.2% (2 mg/mL) eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2253N NP | ‡1 | 5 | .. | 34.74 | 35.95 | Hylo-Forte [AE] |

## ▪ SOY LECITHIN + TOCOPHEROL + VITAMIN A

**Authority required (STREAMLINED)**

***6172***

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**soy lecithin 1% + tocopherol 0.002% + vitamin A palmitate 0.025% eye spray, 100 actuations**

| 5545W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| OP | 2 | 5 | .. | *35.59 | 36.80 | tearsagain [RB] |

**soy lecithin 1% + tocopherol 0.002% + vitamin A palmitate 0.025% eye spray, 100 actuations**

| 9448G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *35.59 | 36.80 | tearsagain [RB] |

# ▪ OTOLOGICALS

## ANTIINFECTIVES

*Antiinfectives*

### ▪ CIPROFLOXACIN

**Authority required**

Chronic suppurative otitis media

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person, **AND**
- Patient must be aged 1 month or older.

**Authority required**

Chronic suppurative otitis media

**Population criteria:**

- Patient must be less than 18 years of age.

**Clinical criteria:**

- Patient must have perforation of the tympanic membrane.

**Authority required**

Chronic suppurative otitis media

**Population criteria:**

- Patient must be less than 18 years of age.

**Clinical criteria:**

- Patient must have a grommet in situ.

**ciprofloxacin 0.3% ear drops, 5 mL**

| 2480M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | .. | 22.27 | 23.48 | Ciloxan [NV] |

## CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION

*Corticosteroids and antiinfectives in combination*

### ▪ FRAMYCETIN SULFATE + GRAMICIDIN + DEXAMETHASONE

**framycetin sulfate 0.5% + gramicidin 0.005% + dexamethasone 0.05% ear drops, 8 mL**

| 2781J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 2 | .. | 14.15 | 15.36 | [a] Otodex [AV] |
| | | | [B]1.66 | 15.81 | 15.36 | [a] Sofradex [SW] |

### ▪ TRIAMCINOLONE + NEOMYCIN SULFATE + GRAMICIDIN + NYSTATIN

**triamcinolone acetonide 0.1% + neomycin sulfate 0.25% + gramicidin 0.025% + nystatin 100 000 international units/mL ear drops, 7.5 mL**

| 2971J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 2 | .. | 15.15 | 16.36 | [a] Otocomb Otic [FM] |
| | | | [B]1.70 | 16.85 | 16.36 | [a] Kenacomb Otic [QA] |

**triamcinolone acetonide 0.1% + neomycin sulfate 0.25% + gramicidin 0.025% + nystatin 100 000 international units/g ointment, 5 g**

| 2974M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 2 | .. | 12.62 | 13.83 | [a] Otocomb Otic [FM] |
| | | | [B]1.70 | 14.32 | 13.83 | [a] Kenacomb Otic [QA] |

# ▪ OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS

## ANTIINFECTIVES

*Antiinfectives*

### ▪ FRAMYCETIN SULFATE

**framycetin sulfate 0.5% eye/ear drops, 8 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1440T NP MW | ‡1 | 2 | .. | 14.67 | 15.88 | Soframycin [SW] |

**framycetin sulfate 0.5% eye/ear drops, 8 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5557L OP | ‡1 | 2 | .. | 14.67 | 15.88 | Soframycin [SW] |

# ▪ VARIOUS

## ▪ ALLERGENS

### ALLERGENS

*Allergen extracts*

### ▪ HONEY BEE VENOM

**bee venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10621B | 1 | .. | .. | 264.51 | 38.80 | Hymenoptera Honey Bee Venom [DE] |

**bee venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2886X | 1 | .. | .. | 264.51 | 38.80 | Albey Bee Venom [DE] |

### ▪ PAPER WASP VENOM

**Note** Paper wasp venom is not European wasp venom

**paper wasp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2918N | 1 | .. | .. | 264.51 | 38.80 | Albey Paper Wasp Venom [DE] |

### ▪ VESPULA SPP VENOM

**vespula spp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2883R | 1 | .. | .. | 264.51 | 38.80 | Albey Yellow Jacket Venom [DE] |

## ▪ ALL OTHER THERAPEUTIC PRODUCTS

### ALL OTHER THERAPEUTIC PRODUCTS

*Antidotes*

### ▪ NALOXONE

**naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10783M NP | 1 | .. | .. | 82.48 | 38.80 | [a] Naloxone Hydrochloride (DBL) [PF] | [a] Naloxone Juno [JU] |

**naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10787R DP | 1 | .. | .. | 82.48 | 38.80 | [a] Naloxone Hydrochloride (DBL) [PF] | [a] Naloxone Juno [JU] |

**naloxone hydrochloride 1 mg/ mL injection, 1 x 2 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11077B DP | 1 | .. | .. | 74.05 | 38.80 | Prenoxad [PL] |

**naloxone hydrochloride 1 mg/ mL injection, 1 x 2 mL syringe**

| 11078C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 74.05 | 38.80 | Prenoxad [PL] |

*Drugs for treatment of hyperkalemia and hyperphosphatemia*

## ▪ LANTHANUM

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***5491***

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90**

| 9403X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 281.53 | 38.80 | Fosrenol [ZI] |

**LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90**

| 9405B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 475.25 | 38.80 | Fosrenol [ZI] |

**LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90**

| 9404Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 422.68 | 38.80 | Fosrenol [ZI] |

## ▪ SEVELAMER

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***5491***

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**sevelamer hydrochloride 800 mg tablet, 180**

| 2142R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 332.52 | 38.80 | Renagel [GZ] |

## ▪ SUCROFERRIC OXYHYDROXIDE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***5491***

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**iron (as sucroferric oxyhydroxide) 500 mg tablet: chewable, 90**

| 10250L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 424.03 | 38.80 | Velphoro [FN] |

*Detoxifying agents for antineoplastic treatment*

## ▪ FOLINIC ACID

**folinic acid 300 mg/30 mL injection, 30 mL vial**

| 9041W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 4 | 1 | .. | *56.39 | 38.80 | [a] Calcium Folinate Ebewe [SZ] | [a] Leucovorin Calcium (Hospira Pty Limited) [PF] |

**folinic acid 1 g/100 mL injection, 100 mL vial**

| 8969C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 49.78 | 38.80 | Calcium Folinate Ebewe [SZ] |

## ▪ FOLINIC ACID

**Note** For item codes 8740B and 1610R, pharmaceutical benefits that have the form injection equivalent to 50 mg folinic acid in 5 mL are equivalent for the purposes of substitution.

**folinic acid 50 mg/5 mL injection, 10 x 5 mL ampoules**

| 1610R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 52.92 | 38.80 | [a] Leucovorin Calcium (Pfizer Australia Pty Ltd) [PF] |

**folinic acid 50 mg/5 mL injection, 5 mL vial**

| 8740B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 10 | 2 | .. | *52.85 | 38.80 | [a] Leucovorin Calcium (Hospira Pty Limited) [PF] |

## ▪ FOLINIC ACID

**Note** For item codes 8812T and 1704Q, pharmaceutical benefits that have the form injection equivalent to 100 mg folinic acid in 10 mL are equivalent for the purposes of substitution.

**folinic acid 100 mg/10 mL injection, 10 mL vial**

| 8812T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 10 | 1 | .. | *58.15 | 38.80 | [a] Calcium Folinate Ebewe [SZ] |

**folinic acid 100 mg/10 mL injection, 10 x 10 mL ampoules**

| 1704Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 58.18 | 38.80 | [a] Leucovorin Calcium (Pfizer Australia Pty Ltd) [PF] |

## ▪ FOLINIC ACID

**Restricted benefit**

Megaloblastic anaemias

**Clinical criteria:**

- The condition must be a result of folic acid deficiency from the use of folic acid antagonists.

**folinic acid 15 mg tablet, 10**

| 2308L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 92.81 | 38.80 | Leucovorin Calcium (Hospira Pty Limited) [PF] |

## ▪ MESNA

**Restricted benefit**

Urothelial toxicity

Treatment Phase: Prophylaxis or reduction of toxicity

**Clinical criteria:**

- The treatment must be adjunctive therapy to ifosfamide or high dose cyclophosphamide.

**mesna 400 mg/4 mL injection, 15 x 4 mL ampoules**

| 8078E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 94.74 | 38.80 | Uromitexan [BX] |

**mesna 1 g/10 mL injection, 15 x 10 mL ampoules**

| 8079F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 200.84 | 38.80 | Uromitexan [BX] |

*Drugs for treatment of hypercalcemia*

## ▪ PHOSPHORUS

**Authority required (STREAMLINED)**
***5089***
Hypophosphataemic rickets
**Authority required (STREAMLINED)**
***5114***
Vitamin D-resistant rickets
**Authority required (STREAMLINED)**
***5095***
Familial hypophosphataemia
**Authority required (STREAMLINED)**
***5123***
Hypercalcaemia

**phosphorus 500 mg effervescent tablet, 100**

| 2946C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 76.04 | 38.80 | Phosphate Sandoz [PL] |

*Other therapeutic products*

## ▪ POLYLACTIC ACID

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Authority applications may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**
Severe facial lipoatrophy
Treatment Phase: Initial PBS-subsidised treatment
**Clinical criteria:**

- The treatment must be for facial administration only, **AND**
- The condition must be caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Galderma is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.

**polylactic acid 150 mg injection, 1 vial**

| 9475Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 4 | .. | *419.77 | 38.80 | Sculptra [GA] |

## ▪ POLYLACTIC ACID

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Maintenance treatment is limited to one re-treatment (maximum 2 vials) every 2 years.
**Note** Authority applications may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**
Severe facial lipoatrophy
Treatment Phase: Maintenance PBS-subsidised treatment
**Clinical criteria:**

- The treatment must be for facial administration only, **AND**
- The condition must be caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Galderma is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.

**polylactic acid 150 mg injection, 1 vial**

| 9476R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *419.77 | 38.80 | Sculptra [GA] |

# DIAGNOSTIC AGENTS

## URINE TESTS

### GLUCOSE AND KETONE INDICATOR URINE

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**glucose and ketone indicator urine diagnostic strip, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3107M NP | 2 | 2 | .. | *20.19 | 21.40 | Keto-Diastix [BN] |

### GLUCOSE INDICATOR URINE

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**glucose indicator urine diagnostic strip, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3104J NP | 2 | 2 | .. | *22.17 | 23.38 | Diastix [BN] |

# GENERAL NUTRIENTS

## OTHER NUTRIENTS

### MEDIUM CHAIN TRIGLYCERIDES

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**
***6147***
Ketogenic diet
**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

**Authority required (STREAMLINED)**
***6191***
Dietary management of conditions requiring a source of medium chain triglycerides
**Clinical criteria:**

- Patient must have chylous ascites; OR
- Patient must have chylothorax; OR
- Patient must have hyperlipoproteinaemia type 1; OR
- Patient must have long chain fatty acid oxidation disorders; OR
- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

**triglycerides medium chain oral liquid, 18 x 250 mL cartons**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10049X NP | 2 | 5 | .. | *357.87 | 38.80 | betaquik [VF] |

### MEDIUM CHAIN TRIGLYCERIDES

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**
***6181***
Chylous ascites
**Authority required (STREAMLINED)**
***6134***
Chylothorax
**Authority required (STREAMLINED)**
***6164***
Fat malabsorption
**Clinical criteria:**

- The condition must be due to liver disease; OR
- The condition must be due to short gut syndrome; OR
- The condition must be due to cystic fibrosis; OR
- The condition must be due to gastrointestinal disorders.

**Authority required (STREAMLINED)**
***6203***
Hyperlipoproteinaemia type 1
**Authority required (STREAMLINED)**
***6155***
Intractable childhood epilepsy
**Clinical criteria:**
- Patient must require a ketogenic diet.

**Authority required (STREAMLINED)**
***6135***
Cerebrospinal fluid glucose transporter defect
**Clinical criteria:**
- Patient must require a ketogenic diet.

**Authority required (STREAMLINED)**
***6146***
Long chain fatty acid oxidation disorders

**medium chain triglycerides oral liquid, 250 mL bottle**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9327X NP | 8 | 5 | .. | *191.63 | 38.80 | Liquigen [SB] |

**medium chain triglycerides oral oil, 500 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3128P NP | 2 | 5 | .. | *50.49 | 38.80 | MCT Oil [SB] |

## ▪ PROTEIN FORMULA WITH CARBOHYDRATE, FAT, VITAMINS AND MINERALS

**Note** No increase in the maximum number of repeats may be authorised.
**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

**Restricted benefit**
Dietary management of conditions requiring a source of medium chain triglycerides
**Clinical criteria:**
- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

**Population criteria:**
- Patient must be aged from 1 to 10 years inclusive.

**protein formula with carbohydrate, fat, vitamins and minerals oral liquid, 8 x 500 mL pouches**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11110R NP | 10 | 5 | .. | *1502.65 | 38.80 | Nutrini Peptisorb Energy [NU] |

## ▪ TRIGLYCERIDES LONG CHAIN

**Note** Carbzero is not nutritionally complete and is not intended for use as a sole source of nutrition.

**Restricted benefit**
Ketogenic diet
**Clinical criteria:**
- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

Carbzero should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

**triglycerides long chain oral liquid, 18 x 250 mL cartons**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10037G NP | 2 | 5 | .. | *289.83 | 38.80 | carbzero [VF] |

*Fat/carbohydrates/proteins/minerals/vitamins, combinations*

## ▪ AMINO ACID SYNTHETIC FORMULA

**Note** Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

**Authority required**
Eosinophilic oesophagitis
Treatment Phase: Initial treatment for up to 3 months
**Treatment criteria:**
- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**amino acid synthetic formula powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1521C NP | 12 | 5 | .. | *501.43 | 38.80 | Neocate Advance Vanilla [SB] |

**amino acid synthetic formula powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2250K NP | 12 | 5 | .. | *501.43 | 38.80 | EleCare [AB] |

## ▪ AMINO ACID SYNTHETIC FORMULA

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**amino acid synthetic formula powder for oral liquid, 400 g**

| 1180D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *335.87 | 38.80 | Neocate Advance Vanilla [SB] |

**amino acid synthetic formula powder for oral liquid, 400 g**

| 8574G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *335.87 | 38.80 | EleCare [AB] |

**amino acid synthetic formula powder for oral liquid, 400 g**

| 8754R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *335.87 | 38.80 | Neocate Advance [SB] |

## ▪ AMINO ACID SYNTHETIC FORMULA

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority required**

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

**amino acid synthetic formula powder for oral liquid, 400 g**

1192R NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 8 | 5 | .. | *335.87 | 38.80 | Neocate Advance Vanilla [SB] |

**amino acid synthetic formula powder for oral liquid, 400 g**

8575H NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 8 | 5 | .. | *335.87 | 38.80 | EleCare [AB] |

**amino acid synthetic formula powder for oral liquid, 400 g**

8755T NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 8 | 5 | .. | *335.87 | 38.80 | Neocate Advance [SB] |

## ▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

| 2246F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *342.43 | 38.80 | Neocate LCP [SB] |

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

| 9339M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *342.43 | 38.80 | EleCare LCP [AB] |

## ▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority required**

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

2560R

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *342.43 | 38.80 | Neocate LCP [SB] |

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

9340N

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *342.43 | 38.80 | EleCare LCP [AB] |

## ▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

**Note** Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1545H NP | 12 | 5 | .. | *511.27 | 38.80 | Neocate Gold [SB] |

## ▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5466Q NP | 8 | 5 | .. | *342.43 | 38.80 | Neocate Gold [SB] |

## ▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority required**

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g**

5467R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 8 | 5 | .. | *342.43 | 38.80 | Neocate Gold [SB] |

NP

## ▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g**

2900P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 8 | 5 | .. | *342.43 | 38.80 | Alfamino [NT] |

NP

## ▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g**

2928D

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *342.43 | 38.80 | Alfamino [NT] |

## ▪ PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***6174***

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

**Population criteria:**

- Patient must be up to the age of 24 months.

**Authority required (STREAMLINED)**

***6193***

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have demonstrated a clinical improvement with the protein hydrolysate formula with medium chain triglycerides.

**Population criteria:**

- Patient must be up to the age of 24 months.

**Authority required (STREAMLINED)**

***6204***

Cows' milk protein enteropathy and intolerance to soy protein

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist must be documented in the patient's medical records

**Authority required (STREAMLINED)**

***6137***

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist must be documented in the patient's medical records

**Authority required (STREAMLINED)**

***6182***

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist must be documented in the patient's medical records

**Authority required (STREAMLINED)**

***6194***

Biliary atresia

**Authority required (STREAMLINED)**

***6157***

Chronic liver failure with fat malabsorption

**Authority required (STREAMLINED)**

***6205***

Chylous ascites

**Authority required (STREAMLINED)**

***6195***

Cystic fibrosis

**Authority required (STREAMLINED)**

***6158***

Enterokinase deficiency

**Authority required (STREAMLINED)**

***6166***
Proven fat malabsorption
**Authority required (STREAMLINED)**
***6148***
Severe diarrhoea of greater than 2 weeks duration
**Population criteria:**
- Patient must be aged less than 4 months.

**Authority required (STREAMLINED)**
***6138***
Severe intestinal malabsorption including short bowel syndrome

**protein hydrolysate formula with medium chain triglycerides powder for oral liquid, 450 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8259Q NP | 8 | 5 | .. | *100.35 | 38.80 | Aptamil Gold+ Pepti-Junior [NU] |

## ▪ PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**
***6174***
Cows' milk protein enteropathy and intolerance to soy protein
Treatment Phase: Initial treatment
**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

**Population criteria:**
- Patient must be up to the age of 24 months.

**Authority required (STREAMLINED)**
***6193***
Cows' milk protein enteropathy and intolerance to soy protein
Treatment Phase: Continuing treatment
**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have demonstrated a clinical improvement with the protein hydrolysate formula with medium chain triglycerides.

**Population criteria:**
- Patient must be up to the age of 24 months.

**Authority required (STREAMLINED)**
***6204***
Cows' milk protein enteropathy and intolerance to soy protein
**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

**Population criteria:**
- Patient must be older than 24 months of age.

The name of the specialist must be documented in the patient's medical records
**Authority required (STREAMLINED)**
***6137***
Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
Treatment Phase: Initial treatment for up to 6 months
**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Population criteria:**
- Patient must be up to the age of 24 months.

The name of the specialist must be documented in the patient's medical records

**Authority required (STREAMLINED)**

***6182***

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist must be documented in the patient's medical records

**Authority required (STREAMLINED)**

***6194***

Biliary atresia

**Authority required (STREAMLINED)**

***6157***

Chronic liver failure with fat malabsorption

**Authority required (STREAMLINED)**

***6205***

Chylous ascites

**Authority required (STREAMLINED)**

***6195***

Cystic fibrosis

**Authority required (STREAMLINED)**

***6158***

Enterokinase deficiency

**Authority required (STREAMLINED)**

***6166***

Proven fat malabsorption

**Authority required (STREAMLINED)**

***6148***

Severe diarrhoea of greater than 2 weeks duration

**Population criteria:**

- Patient must be aged less than 4 months.

**Authority required (STREAMLINED)**

***6138***

Severe intestinal malabsorption including short bowel syndrome

**Authority required (STREAMLINED)**

***6206***

Chylothorax

**protein hydrolysate formula with medium chain triglycerides powder for oral liquid, 400 g**

| 2676W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *154.03 | 38.80 | Alfaré [NT] |

## ▪ TRIGLYCERIDES MEDIUM CHAIN FORMULA

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

**Restricted benefit**

Dietary management of conditions requiring a source of medium chain triglycerides

**Clinical criteria:**

- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

**triglycerides medium chain formula powder for oral liquid, 400 g**

| 10152H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *394.99 | 38.80 | Monogen [SB] |

**triglycerides medium chain formula powder for oral liquid, 400 g**

| 10155L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *416.11 | 38.80 | Lipistart [VF] |

**triglycerides medium chain formula oral liquid, 8 x 500 mL pouches**

| 10375C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *824.43 | 38.80 | Nutrini Peptisorb [SB] |

## ▪ TRIGLYCERIDES MEDIUM CHAIN FORMULA

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

**Restricted benefit**

Dietary management of conditions requiring a source of medium chain triglycerides

**Clinical criteria:**

- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

**triglycerides medium chain formula powder for oral liquid, 400 g**

| 10154K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *385.31 | 38.80 | Peptamen Junior [NT] |

## ▪ TRIGLYCERIDES MEDIUM CHAIN FORMULA

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

**Restricted benefit**

Hyperlipoproteinaemia type 1

**Restricted benefit**

Long chain fatty acid oxidation disorders

**Restricted benefit**

Chylous ascites

**Restricted benefit**

Chylothorax

**triglycerides medium chain formula powder for oral liquid, 400 g**

| 1938B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *416.11 | 38.80 | Lipistart [VF] |

**triglycerides medium chain formula powder for oral liquid, 400 g**

| 8478F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *394.99 | 38.80 | Monogen [SB] |

*Carbohydrates*

## ▪ MODIFIED LONG CHAIN AMYLOPECTIN

**Restricted benefit**

Glycogen storage disease

**modified long chain amylopectin powder for oral liquid, 30 x 60 g sachets**

| 9386B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *709.95 | 38.80 | Glycosade [VF] |

*Amino acids/carbohydrates/minerals/vitamins, combinations*

## ▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**

- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides oral liquid: powder for, 400 g**

| 10522T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *353.31 | 38.80 | Alfamino Junior [NT] |

## ▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides oral liquid: powder for, 400 g**

10527C

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 8 | 5 | .. | *353.31 | 38.80 | Alfamino Junior [NT] |

## ▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g**

| 11161K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *353.31 | 38.80 | Neocate Junior [SB] |

## ▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g**

| 11183N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *353.31 | 38.80 | Neocate Junior [SB] |

*Milk substitutes*

## ▪ MILK POWDER LACTOSE FREE FORMULA

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Chronic lactose intolerance

**Population criteria:**

- Patient must be up to the age of 12 months.

**Clinical criteria:**

- The condition must be proven to be lactose intolerance.

Lactose intolerance must have been proven by either:

(a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or

(b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or

(c) hydrogen breath test.

The date of birth of the patient must be included in the authority application.

**milk powder lactose free formula powder for oral liquid, 900 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8283Y NP | 5 | 5 | .. | *103.05 | 38.80 | S-26 LF [AS] |

## ▪ MILK POWDER LACTOSE FREE FORMULA

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** No more than 1 application per patient will be authorised.

**Authority required**

Acute lactose intolerance

**Population criteria:**

- Patient must be up to the age of 12 months.

The date of birth of the patient must be included in the authority application.

**milk powder lactose free formula powder for oral liquid, 900 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8282X NP | 5 | .. | .. | *103.05 | 38.80 | S-26 LF [AS] |

## ▪ MILK POWDER LACTOSE FREE FORMULA PREDIGESTED

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Chronic lactose intolerance

**Population criteria:**

- Patient must be up to the age of 12 months.

**Clinical criteria:**

- The condition must be proven to be lactose intolerance.

Lactose intolerance must have been proven by either:

(a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or

(b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or

(c) hydrogen breath test.

The date of birth of the patient must be included in the authority application.

**milk powder lactose free formula predigested powder for oral liquid, 900 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2989H NP | 5 | 5 | .. | *88.00 | 38.80 | Aptamil Gold+ De-Lact [NU] |

## ▪ MILK POWDER LACTOSE FREE FORMULA PREDIGESTED

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** No more than 1 application per patient will be authorised.

**Authority required**

Acute lactose intolerance

**Population criteria:**

- Patient must be up to the age of 12 months.

The date of birth of the patient must be included in the authority application.

**milk powder lactose free formula predigested powder for oral liquid, 900 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2975N NP | 5 | .. | .. | *88.00 | 38.80 | Aptamil Gold+ De-Lact [NU] |

## ▪ MILK POWDER SYNTHETIC LOW CALCIUM

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Hypercalcaemia

**Population criteria:**

- Patient must be under the age of 4 years.

**milk powder synthetic low calcium powder for oral liquid, 400 g**

| 3092R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *355.87 | 38.80 | Locasol [SB] |

*Other combinations of nutrients*

- **AMINO ACID FORMULA WITH CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE**

**Restricted benefit**

Phenylketonuria

**amino acid formula with carbohydrate, vitamins, minerals and trace elements without phenylalanine oral liquid: powder for, 30 x 20 g sachets**

| 10806R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *1000.43 | 38.80 | PKU Go [OH] |

- **AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE**

**Restricted benefit**

Phenylketonuria

**amino acid formula with fat, carbohydrate without phenylalanine tablet: modified release, 4 x 110 g**

| 10683G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 7 | 5 | .. | *1929.63 | 38.80 | PKU Easy Microtabs [OH] |

- **AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID**

**Restricted benefit**

Phenylketonuria

**amino acid formula with fat, carbohydrate, vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine and supplemented with docosahexaenoic acid oral liquid, 20 x 500 mL bottles**

| 10822N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *633.75 | 38.80 | PKU Baby [OH] |

- **AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT METHIONINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID**

**Restricted benefit**

Pyridoxine non-responsive homocystinuria

**amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without methionine and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL cans**

| 3417W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *2393.07 | 38.80 | HCU Anamix junior LQ [SB] |

- **AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE**

**Restricted benefit**

Phenylketonuria

**amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine oral liquid: powder for, 30 x 34 g bottles**

| 10632N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 5 | 5 | .. | *1905.85 | 38.80 | PKU Easy Shake & Go [OH] |

- **AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE AND TYROSINE**

**Restricted benefit**

Tyrosinaemia

**amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine oral liquid: powder for, 30 x 34 g bottles**

| 10934L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *2953.95 | 38.80 | TYR Easy Shake & Go [OH] |

- **AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE AND TYROSINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID**

**Restricted benefit**

Tyrosinaemia

**amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL cans**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9330C NP | 4 | 5 | .. | *2393.07 | 38.80 | TYR Anamix junior LQ [SB] |

- **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN**

**Restricted benefit**

Proven glutaric aciduria type 1

**amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 30 x 18 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10715Y NP | 8 | 5 | .. | *2012.19 | 38.80 | GA1 Anamix Junior [NU] |

- **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN**

**Restricted benefit**

Proven glutaric aciduria type 1

**amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 30 x 25 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5484P NP | 4 | 5 | .. | *3007.19 | 38.80 | GA express 15 [VF] |

**amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 30 x 24 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9438R NP | 4 | 5 | .. | *2012.23 | 38.80 | GA gel [VF] |

**amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2650L NP | 8 | 5 | .. | *726.03 | 38.80 | GA1 Anamix infant [SB] |

**amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 500 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10466W NP | 9 | 5 | .. | *2935.75 | 38.80 | XLYS, LOW TRY Maxamum [SB] |

- **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE**

**Restricted benefit**

Pyridoxine non-responsive homocystinuria

**amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 174 mL sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2640Y NP | 4 | 5 | .. | *3888.75 | 38.80 | HCU cooler 20 [VF] |

**amino acid formula with vitamins and minerals without methionine powder for oral liquid, 500 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8416Y NP | 8 | 5 | .. | *2579.95 | 38.80 | XMET Maxamum [SB] |

**amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 130 mL cans**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9133Q NP | 4 | 5 | .. | *2953.95 | 38.80 | HCU cooler 15 [VF] |

**amino acid formula with vitamins and minerals without methionine powder for oral liquid, 30 x 24 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8677Q NP | 4 | 5 | .. | *2012.23 | 38.80 | HCU gel [VF] |

**amino acid formula with vitamins and minerals without methionine powder for oral liquid, 30 x 25 g sachets**

| 8744F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *2953.95 | 38.80 | HCU express 15 [VF] |

**AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE Oral liquid 125 mL, 30, 1**

| 1548L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 5 | .. | *2953.90 | 38.80 | HCU Lophlex LQ 20 [SB] |

**amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 87 mL sachets**

| 2639X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *2012.23 | 38.80 | HCU cooler 10 [VF] |

- **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE**

  **Restricted benefit**

  Pyridoxine non-responsive homocystinuria

**amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 30 x 36 g sachets**

| 10693T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *2012.23 | 38.80 | HCU Anamix Junior [NU] |

- **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE**

  **Restricted benefit**

  Pyridoxine non-responsive homocystinuria

  **Population criteria:**

  - Patient must be an infant or a very young child.

**amino acid formula with vitamins and minerals without methionine powder for oral liquid, 400 g**

| 8417B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *726.03 | 38.80 | HCU Anamix infant [SB] |

- **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE**

  **Restricted benefit**

  Methylmalonic acidaemia

  **Restricted benefit**

  Propionic acidaemia

**amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 30 x 25 g sachets**

| 3443F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *2953.95 | 38.80 | MMA/PA express 15 [VF] |

**AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE, THREONINE and VALINE and low in ISOLEUCINE Oral liquid 130 mL, 30, 1**

| 1923F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *2953.95 | 38.80 | MMA/PA cooler 15 [VF] |

**amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 500 g**

| 8061G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *2579.95 | 38.80 | XMTVI Maxamum [SB] |

**amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 30 x 24 g sachets**

| 3444G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *2012.23 | 38.80 | MMA/PA gel [VF] |

**amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 400 g**

| 8058D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *726.03 | 38.80 | MMA/PA Anamix infant [SB] |

- **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE**

  **Restricted benefit**

Methylmalonic acidaemia
**Restricted benefit**
Propionic acidaemia

**amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 30 x 18 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10730R NP | 8 | 5 | .. | *2012.19 | 38.80 | MMA/PA Anamix Junior [NU] |

## ▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE

**Restricted benefit**
Phenylketonuria

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 174 mL pouch**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10411Y NP | 4 | 5 | .. | *1952.87 | 38.80 | PKU Air 20 [VF] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 87 mL cans**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2382J NP | 4 | 5 | .. | *976.99 | 38.80 | PKU Cooler 10 [VF] |

**amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 50 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8727H NP | 3 | 5 | .. | *1431.91 | 38.80 | XP Maxamum [SB] |

**amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 24 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8555G NP | 4 | 5 | .. | *1000.43 | 38.80 | PKU gel [VF] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 18 x 250 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8746H NP | 5 | 5 | .. | *1243.95 | 38.80 | Easiphen [SB] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 125 mL cans**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9021T NP | 3 | 5 | .. | *1467.25 | 38.80 | PKU Lophlex LQ 20 [SB] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 130 mL cans**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8846N NP | 4 | 5 | .. | *1466.15 | 38.80 | PKU Cooler 15 [VF] |

**amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 500 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2738D NP | 8 | 5 | .. | *834.51 | 38.80 | XP Maxamaid [SB] |

**amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 500 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2739E NP | 8 | 5 | .. | *1280.99 | 38.80 | XP Maxamum [SB] |

**amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 27.8 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8804J NP | 3 | 5 | .. | *1467.25 | 38.80 | Lophlex [SB] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 36 x 125 mL cans**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9396M NP | 4 | 5 | .. | *1202.91 | 38.80 | PKU Anamix Junior LQ [SB] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 174 mL cans**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2474F NP | 4 | 5 | .. | *1952.87 | 38.80 | PKU Cooler 20 [VF] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 85 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5483N NP | 4 | 5 | .. | *1000.43 | 38.80 | PKU squeezie [VF] |

**amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 25 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8591E NP | 4 | 5 | .. | *1466.95 | 38.80 | PKU express 15 [VF] |

**amino acid formula with vitamins and minerals without phenylalanine oral semi-solid, 36 x 109 g jars**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2806Q NP | 3 | 5 | .. | *1754.98 | 38.80 | PKU Lophlex Sensation 20 [SB] |

**AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE Sachets 34 g, 30, 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1909L NP | 4 | 5 | .. | *1952.87 | 38.80 | PKU express 20 [VF] |

**AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE Sachets 18.2 g, 60, 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1411G NP | 3 | 5 | .. | *1552.93 | 38.80 | add-ins [SB] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 130 mL pouch**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10410X NP | 4 | 5 | .. | *1466.15 | 38.80 | PKU Air 15 [VF] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 60 x 62.5 mL cans**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9397N NP | 2 | 5 | .. | *1001.21 | 38.80 | PKU Lophlex LQ 10 [SB] |

## ▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE

**Note** Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

**Restricted benefit**
Phenylketonuria

**amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 36 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10258X NP | 4 | 5 | .. | *1001.63 | 38.80 | PKU Anamix Junior [SB] |

## ▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE

**Restricted benefit**
Tyrosinaemia

**AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE and TYROSINE Oral liquid 125 mL, 30, 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1547K NP | 3 | 5 | .. | *2953.90 | 38.80 | TYR Lophlex LQ 20 [SB] |

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 174 mL sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2701E NP | 4 | 5 | .. | *3888.75 | 38.80 | TYR cooler 20 [VF] |

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 500 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3078B NP | 8 | 5 | .. | *2579.95 | 38.80 | XPhen, Tyr Maxamum [SB] |

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 30 x 34 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11151X NP | 4 | 5 | .. | *3888.75 | 38.80 | TYR express 20 [VF] |

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 30 x 24 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8631G NP | 4 | 5 | .. | *2012.23 | 38.80 | TYR gel [VF] |

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 30 x 25 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8667E NP | 4 | 5 | .. | *2953.95 | 38.80 | TYR express 15 [VF] |

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 130 mL cans**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9132P NP | 4 | 5 | .. | *2953.95 | 38.80 | TYR cooler 15 [VF] |

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 87 mL sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2674R NP | 4 | 5 | .. | *2012.23 | 38.80 | TYR cooler 10 [VF] |

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8445L NP | 8 | 5 | .. | *726.03 | 38.80 | TYR Anamix infant [SB] |

## ▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE

**Note** Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

**Restricted benefit**

Tyrosinaemia

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 36 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10260B NP | 4 | 5 | .. | *2012.23 | 38.80 | TYR Anamix Junior [SB] |

## ▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE

**Restricted benefit**

Maple syrup urine disease

**AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE Sachets 34 g, 30, 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1914R NP | 4 | 5 | .. | *3899.91 | 38.80 | MSUD express 20 [VF] |

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 130 mL cans**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2375B NP | 4 | 5 | .. | *2953.95 | 38.80 | MSUD cooler 15 [VF] |

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2380G NP | 8 | 5 | .. | *726.03 | 38.80 | MSUD Anamix infant [SB] |

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 87 mL pouches**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2651M NP | 4 | 5 | .. | *2012.23 | 38.80 | MSUD cooler 10 [VF] |

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 174 mL pouches**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2654Q NP | 4 | 5 | .. | *3888.75 | 38.80 | MSUD cooler 20 [VF] |

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 500 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8057C NP | 8 | 5 | .. | *2579.95 | 38.80 | MSUD Maxamum [SB] |

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 500 g**

| 8310J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *2548.87 | 38.80 | MSUD AID III [SB] |

**AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE Oral liquid 125 mL, 30, 1**

| 1546J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 5 | .. | *2953.90 | 38.80 | MSUD Lophlex LQ 20 [SB] |

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 30 x 25 g sachets**

| 8632H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *2953.95 | 38.80 | MSUD express 15 [VF] |

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 30 x 24 g sachets**

| 8592F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *2012.23 | 38.80 | MSUD gel [VF] |

## ▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE

**Note** Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

**Restricted benefit**

Maple syrup urine disease

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 36 g sachets**

| 10259Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *2012.23 | 38.80 | MSUD Anamix Junior [SB] |

## ▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE WITH FAT, CARBOHYDRATE AND TRACE ELEMENTS AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID

**Restricted benefit**

Maple syrup urine disease

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL cans**

| 9499Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *2393.07 | 38.80 | MSUD Anamix Junior LQ [SB] |

## ▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS, LOW PHENYLALANINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID AND ARACHIDONIC ACID

**Restricted benefit**

Phenylketonuria

**amino acid formula with vitamins and minerals, low phenylalanine and supplemented with docosahexaenoic acid and arachidonic acid powder for oral liquid, 30 x 12.5 g sachets**

| 11185Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *1000.35 | 38.80 | PKU Anamix First Spoon [SB] |

## ▪ AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE

**Restricted benefit**

Phenylketonuria

**amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine powder for oral liquid, 400 g**

| 8479G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *663.95 | 38.80 | PKU Anamix infant [SB] |

## ▪ AMINO ACID FORMULA WITHOUT PHENYLALANINE

**Restricted benefit**

Phenylketonuria

**amino acid formula without phenylalanine 500 mg capsule, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8554F NP | 16 | 5 | .. | *1209.07 | 38.80 | Phlexy-10 [SB] |

**amino acid formula without phenylalanine powder for oral liquid, 30 x 20 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2347M NP | 7 | 5 | .. | *1385.45 | 38.80 | Phlexy-10 Drink Mix [SB] |

**amino acid formula without phenylalanine 1 g tablet, 75**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8678R NP | 24 | 5 | .. | *1351.39 | 38.80 | Phlexy-10 [SB] |

## ▪ AMINO ACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE

**Restricted benefit**

Maple syrup urine disease

**amino acid formula without valine, leucine and isoleucine containing 5 g of protein equivalent oral liquid: powder for, 30 x 6 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10161T NP | 12 | 5 | .. | *3101.59 | 38.80 | MSUD amino5 [VF] |

## ▪ ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE

**Restricted benefit**

Peroxisomal biogenesis disorders

**arachidonic acid and docosahexaenoic acid with carbohydrate containing 200 mg arachidonic acid and 100 mg docosahexaenoic acid oral liquid: powder for, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10036F NP | 4 | 5 | .. | *363.31 | 38.80 | keyomega [VF] |

## ▪ ARGININE WITH CARBOHYDRATE

**Note** Arginine with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.

**Restricted benefit**

Urea cycle disorders

**arginine with carbohydrate containing 500 mg arginine oral liquid: powder for, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9437Q NP | 4 | 5 | .. | *486.55 | 38.80 | Arginine 500 [VF] |

**arginine with carbohydrate containing 2 g arginine oral liquid: powder for, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5482M NP | 4 | 5 | .. | *727.51 | 38.80 | Arginine 2000 [VF] |

**arginine with carbohydrate containing 5 g arginine oral liquid: powder for, 30 x 7.6 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10093F NP | 4 | 5 | .. | *966.03 | 38.80 | Arginine 5000 [VF] |

## ▪ CARBOHYDRATE, FAT, VITAMINS, MINERALS AND TRACE ELEMENTS

**Restricted benefit**

Proven inborn errors of protein metabolism

**Clinical criteria:**

- Patient must be unable to meet their energy requirements with permitted food and formulae.

**carbohydrate, fat, vitamins, minerals and trace elements powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8369L NP | 8 | 5 | .. | *293.63 | 38.80 | Energivit [SB] |

## ▪ CARBOHYDRATES, FAT, VITAMINS, MINERALS, TRACE ELEMENTS AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID

**Restricted benefit**

Proven inborn errors of protein metabolism

**Clinical criteria:**

- Patient must be unable to meet their energy requirements with permitted food and formulae.

**carbohydrates, fat, vitamins, minerals, trace elements and supplemented with arachidonic acid and docosahexaenoic acid providing 100 kilocalories powder for oral liquid, 30 x 21.5 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10050Y NP | 4 | 5 | .. | *236.47 | 38.80 | basecal 100 [VF] |

**carbohydrates, fat, vitamins, minerals, trace elements and supplemented with arachidonic acid and docosahexaenoic acid providing 200 kilocalories powder for oral liquid, 30 x 43 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10039J NP | 4 | 5 | .. | *468.19 | 38.80 | basecal 200 [VF] |

## ▪ CITRULLINE

**Note** Citrulline is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism

**Restricted benefit**

Urea cycle disorders

**Clinical criteria:**

- The treatment must be for preventing low plasma arginine levels; OR
- The treatment must be for preventing low citrulline levels.

**citrulline 1 g tablet, 300**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10736C NP | ‡1 | 5 | .. | 1197.40 | 38.80 | Citrulline Easy [OH] |

## ▪ CITRULLINE WITH CARBOHYDRATE

**Note** Citrulline with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.

**Restricted benefit**

Urea cycle disorders

**Clinical criteria:**

- The treatment must be for preventing low plasma arginine levels; OR
- The treatment must be for preventing low citrulline levels.

**citrulline with carbohydrate containing 1 g citrulline oral liquid: powder for, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5481L NP | 4 | 5 | .. | *486.55 | 38.80 | Citrulline 1000 [VF] |

## ▪ CYSTINE WITH CARBOHYDRATE

**Restricted benefit**

Pyridoxine non-responsive homocystinuria

**cystine with carbohydrate containing 500 mg cystine oral liquid: powder for, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9164H NP | 4 | 5 | .. | *486.55 | 38.80 | Cystine 500 [VF] |

## ▪ DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE

**Restricted benefit**

Peroxisomal biogenesis disorders

**docosahexaenoic acid with carbohydrate containing 200 mg docosahexaenoic acid oral liquid: powder for, 30 x 4g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10040K NP | 4 | 5 | .. | *363.31 | 38.80 | docomega [VF] |

## ▪ ESSENTIAL AMINO ACIDS FORMULA

**Restricted benefit**

Gyrate atrophy of the choroid and retina

**Restricted benefit**

Urea cycle disorders

**essential amino acids formula powder for oral liquid, 2 x 200 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9329B NP | 6 | 5 | .. | *1137.37 | 38.80 | Essential Amino Acid Mix [SB] |

## ▪ ESSENTIAL AMINO ACIDS FORMULA WITH MINERALS AND VITAMIN C

**Restricted benefit**

Gyrate atrophy of the choroid and retina

**Restricted benefit**

Urea cycle disorders

**essential amino acids formula with minerals and vitamin C powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2027Q NP | 5 | 5 | .. | *598.30 | 38.80 | Dialamine [SB] |

## ▪ ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS

**Restricted benefit**

Gyrate atrophy of the choroid and retina

**Restricted benefit**

Urea cycle disorders

**essential amino acids formula with vitamins and minerals powder for oral liquid, 50 x 12.5 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9385Y NP | 4 | 5 | .. | *1436.07 | 38.80 | EAA Supplement [VF] |

## ▪ GLYCINE WITH CARBOHYDRATE

**Restricted benefit**

Isovaleric acidaemia

**glycine with carbohydrate containing 500 mg of glycine oral liquid: powder for, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10195N NP | 4 | 5 | .. | *511.95 | 38.80 | Glycine500 [VF] |

## ▪ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

**Restricted benefit**

Phenylketonuria

**glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 81 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2644E NP | 14 | 5 | .. | *1288.71 | 38.80 | Camino Pro Complete [QH] |

**glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 54 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2696X NP | 14 | 5 | .. | *860.73 | 38.80 | Camino Pro Complete [QH] |

**glycomacropeptide and essential amino acids with vitamins and minerals oral liquid: powder for, 30 x 49 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10652P NP | 4 | 5 | .. | *1570.63 | 38.80 | Camino Pro Bettermilk [QH] |

## ▪ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

**Note** This product contains higher vitamin A levels than other PBS-listed glycomacropeptide products.

**Restricted benefit**

Phenylketonuria

**glycomacropeptide and essential amino acids with vitamins and minerals containing 10 g protein oral liquid, 30 x 250 mL cartons**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10359F NP | 4 | 5 | .. | *1072.79 | 38.80 | PKU Glytactin RTD 10 [QH] |

**glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g protein oral liquid, 30 x 250 mL cartons**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10332T NP | 4 | 5 | .. | *1570.59 | 38.80 | PKU Glytactin RTD 15 [QH] |

## ▪ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

**Restricted benefit**

Tyrosinaemia

**glycomacropeptide and essential amino acids with vitamins and minerals 15 g protein equivalent oral liquid, 30 x 250 mL cartons**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10528D NP | 4 | 5 | .. | *3101.55 | 38.80 | Tylactin RTD [QH] |

## ▪ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

**Restricted benefit**

Phenylketonuria

**glycomacropeptide and essential amino acids with vitamins and minerals powder for oral liquid, 30 x 51 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10992M NP | 4 | 5 | .. | *2068.43 | 38.80 | PKU Bettermilk Lite [QH] |

**glycomacropeptide and essential amino acids with vitamins and minerals powder for oral liquid, 60 x 20 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11084J NP | 5 | 5 | .. | *1311.85 | 38.80 | PKU Restore [QH] |

## ▪ GLYCOMACROPEPTIDE FORMULA WITH LONG CHAIN POLYUNSATURATED FATTY ACID AND DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE

**Restricted benefit**

Phenylketonuria

**glycomacropeptide formula with long chain polyunsaturated fatty acid and docosahexaenoic acid and low phenylalanine powder for oral liquid, 30 x 35 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11071Q NP | 4 | 5 | .. | *2068.43 | 38.80 | PKU Sphere [VF] |

## ▪ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

**Note** Authorities for increased maximum quantities, up to a maximum of 11, may be authorised.

**Restricted benefit**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

Keyo should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

**high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate oral semi-solid, 48 x 100 g tubs**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11108P NP | 3 | 5 | .. | *866.05 | 38.80 | Keyo [VF] |

## ▪ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

**Note** Authorities for increased maximum quantities, up to a maximum of 11, may be authorised.

**Restricted benefit**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

KetoCal 4:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

**high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydrate plus protein) oral liquid, 32 x 200 mL cartons**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10185C NP | 5 | 5 | .. | *931.85 | 38.80 | KetoCal 4:1 LQ [SB] |

## ▪ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

**Note** Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.

**Restricted benefit**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

KetoCal 3:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

**high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (3:1 ratio long chain fat to carbohydrate plus protein) powder for oral liquid, 300 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2652N NP | 24 | 5 | .. | *979.63 | 38.80 | KetoCal 3:1 [SB] |

## ▪ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

**Note** Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.

**Restricted benefit**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

KetoCal 4:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

**high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydate plus protein) powder for oral liquid, 300 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9446E NP | 24 | 5 | .. | *979.63 | 38.80 | KetoCal 4:1 [SB] |

## ▪ ISOLEUCINE WITH CARBOHYDRATE

**Restricted benefit**

Maple syrup urine disease

**isoleucine with carbohydrate containing 1 g isoleucine oral liquid: powder for, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9436P NP | 4 | 5 | .. | *534.75 | 38.80 | Isoleucine 1000 [VF] |

**isoleucine with carbohydrate containing 50 mg isoleucine oral liquid: powder for, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9134R NP | 4 | 5 | .. | *486.55 | 38.80 | Isoleucine 50 [VF] |

## ▪ MILK PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE

**Restricted benefit**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency; OR
- Patient must be an infant or young child with glucose-galactose intolerance and multiple monosaccharide intolerance.

**milk protein and fat formula with vitamins and minerals carbohydrate free powder for oral liquid, 225 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8630F NP | 24 | 5 | .. | *611.71 | 38.80 | Carbohydrate Free Mixture [SB] |

## ▪ PHENYLALANINE WITH CARBOHYDRATE

**Restricted benefit**

Tyrosinaemia

**phenylalanine with carbohydrate containing 50 mg phenylalanine oral liquid: powder for, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9384X NP | 4 | 5 | .. | *486.55 | 38.80 | Phenylalanine 50 [VF] |

## ▪ PROTEIN FORMULA WITH AMINO ACIDS, CARBOHYDRATES, VITAMINS AND MINERALS WITHOUT PHENYLALANINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID

**Restricted benefit**

Phenylketonuria

**protein formula with amino acids, carbohydrates, vitamins and minerals without phenylalanine, and supplemented with docosahexaenoic acid oral liquid, 30 x 130 mL pouches**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10658Y NP | 5 | 5 | .. | *1904.80 | 38.80 | PKU Easy [OH] |

## ▪ SOY PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE

**Restricted benefit**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency; OR
- Patient must be an infant or young child with glucose-galactose intolerance and multiple monosaccharide intolerance.

**soy protein and fat formula with vitamins and minerals carbohydrate free oral liquid, 384 mL can**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8577K NP | 120 | 5 | .. | *632.35 | 38.80 | RCF [AB] |

## ▪ TRIGLYCERIDES LONG CHAIN WITH GLUCOSE POLYMER

**Restricted benefit**

Proven inborn errors of protein metabolism

**Clinical criteria:**

- Patient must be unable to meet their energy requirements with permitted food and formulae.

**triglycerides long chain with glucose polymer oral liquid, 6 x 1 L bottles**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9309Y NP | 4 | 5 | .. | *279.67 | 38.80 | ProZero [VF] |

**triglycerides long chain with glucose polymer oral liquid, 27 x 200 mL cartons**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10189G NP | 2 | 5 | .. | *171.23 | 38.80 | Sno-Pro [SB] |

**triglycerides long chain with glucose polymer oral liquid, 18 x 250 mL cans**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9308X NP | 6 | 5 | .. | *314.83 | 38.80 | ProZero [VF] |

## ▪ TRIGLYCERIDES MEDIUM CHAIN AND LONG CHAIN WITH GLUCOSE POLYMER

**Restricted benefit**

Proven inborn errors of protein metabolism

**Clinical criteria:**

- Patient must be unable to meet their energy requirements with permitted food and formulae.

**triglycerides medium chain and long chain with glucose polymer powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3136C NP | 8 | 5 | .. | *271.31 | 38.80 | Duocal [SB] |

## ▪ TRIGLYCERIDES MEDIUM CHAIN FORMULA

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

**Authority required (STREAMLINED)**

***6165***

Chylous ascites

**Authority required (STREAMLINED)**

***6192***

Chylothorax

**Authority required (STREAMLINED)**

***6173***

Fat malabsorption

**Clinical criteria:**

- The condition must be due to liver disease; OR
- The condition must be due to short gut syndrome; OR
- The condition must be due to cystic fibrosis; OR
- The condition must be due to gastrointestinal disorders.

**Authority required (STREAMLINED)**

***6156***

Hyperlipoproteinaemia type 1

**Authority required (STREAMLINED)**

***6136***

Long chain fatty acid oxidation disorders

**triglycerides medium chain formula powder for oral liquid, 30 x 16 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9383W NP | 4 | 5 | .. | *230.19 | 38.80 | MCT Pro-Cal [VF] |

## ▪ TYROSINE WITH CARBOHYDRATE

**Restricted benefit**

Phenylketonuria

**tyrosine with carbohydrate containing 1 g tyrosine oral liquid: powder for, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9165J NP | 4 | 5 | .. | *486.55 | 38.80 | Tyrosine 1000 [VF] |

## ▪ VALINE WITH CARBOHYDRATE

**Restricted benefit**

Maple syrup urine disease

**valine with carbohydrate containing 50 mg valine oral liquid: powder for, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9135T NP | 4 | 5 | .. | *486.55 | 38.80 | Valine 50 [VF] |

**valine with carbohydrate containing 1 g valine oral liquid: powder for, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9434M NP | 4 | 5 | .. | *534.75 | 38.80 | Valine 1000 [VF] |

## ▪ VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE

**Note** FruitiVits must only be used under strict supervision of a dietitian and a paediatrician.

**Restricted benefit**

Dietary management of conditions requiring a highly restrictive therapeutic diet

**Clinical criteria:**

- Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, **AND**
- Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

**Population criteria:**

- Patient must be aged 3 years or older.

**vitamins, minerals and trace elements with carbohydrate powder for oral liquid, 30 x 6 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10149E NP | 1 | 5 | .. | 274.69 | 38.80 | FruitiVits [VF] |

## ▪ VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE

**Note** Paediatric Seravit must only be used under strict supervision of a dietitian and a paediatrician.

**Restricted benefit**

Dietary management of conditions requiring a highly restrictive therapeutic diet

**Clinical criteria:**

- Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, **AND**
- Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

**Population criteria:**

- Patient must be an infant or a child.

**vitamins, minerals and trace elements with carbohydrate powder for oral liquid, 200 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9328Y NP | 6 | 5 | .. | *364.57 | 38.80 | Paediatric Seravit [SB] |

## ▪ WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE

**Authority required (STREAMLINED)**

***6190***

Chronic renal failure

**Population criteria:**

- Patient must be an infant or a young child.

**Clinical criteria:**

- Patient must require treatment with a low protein and a low phosphorus diet; OR

- Patient must require treatment with a low protein, low phosphorus and low potassium diet.

**whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose powder for oral liquid, 10 x 100 g sachets**

| 9382T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 9 | 5 | .. | *1406.92 | 38.80 | RenaStart [VF] |

**whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose oral liquid: powder for, 6 x 400 g cans**

| 2870C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *1500.15 | 38.80 | Renastart [VF] |

## ▪ WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE

**Authority required (STREAMLINED)**

***6190***

Chronic renal failure

**Population criteria:**

- Patient must be an infant or a young child.

**Clinical criteria:**

- Patient must require treatment with a low protein and a low phosphorus diet; OR
- Patient must require treatment with a low protein, low phosphorus and low potassium diet.

**whey protein formula supplemented with amino acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose powder for oral liquid, 400 g**

| 8587Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 16 | 5 | .. | *1007.95 | 38.80 | Kindergen [SB] |

# Palliative Care

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Palliative

# ALIMENTARY TRACT AND METABOLISM

## STOMATOLOGICAL PREPARATIONS

### STOMATOLOGICAL PREPARATIONS

*Other agents for local oral treatment*

#### BENZYDAMINE

**Authority required (STREAMLINED)**

***6197***

Painful mouth

**Clinical criteria:**

- Patient must be receiving palliative care.

**benzydamine hydrochloride 0.15% mouthwash, 500 mL**

| 5385K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 3 | .. | 24.18 | 25.39 | Difflam [IA] |

## DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

### BELLADONNA AND DERIVATIVES, PLAIN

*Belladonna alkaloids, semisynthetic, quaternary ammonium compounds*

#### HYOSCINE BUTYLBROMIDE

**Authority required (STREAMLINED)**

***6207***

For use in patients receiving palliative care

**hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules**

| 5317W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 6 | 3 | .. | *99.31 | 38.80 | Buscopan [VZ] |

### PROPULSIVES

*Propulsives*

#### METOCLOPRAMIDE

**Authority required (STREAMLINED)**

***6084***

Nausea or gastric stasis

**Clinical criteria:**

- Patient must be receiving palliative care.

**metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules**

| 10762K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | .. | .. | *33.95 | 35.16 | Maxolon [IA] |

## DRUGS FOR CONSTIPATION

### DRUGS FOR CONSTIPATION

*Contact laxatives*

#### BISACODYL

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**bisacodyl 10 mg suppository, 12**

| 5304E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 3 | .. | *21.43 | 22.64 | Petrus Bisacodyl Suppositories [PP] |

**bisacodyl 5 mg enteric tablet, 200**

| 5301B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 3 | .. | 16.36 | 17.57 | Lax-Tab [AE] |

**bisacodyl 10 mg suppository, 10**

| 5303D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 3 | .. | *23.71 | 24.92 | [a] Petrus Bisacodyl Suppositories [PP] |
| | | | [B]1.29 | *25.00 | 24.92 | [a] Dulcolax [VZ] |

*Bulk-forming laxatives*

## ▪ RHAMNUS FRANGULA + STERCULIA

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g**

| 5322D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 3 | .. | 27.57 | 28.78 | Normacol Plus [NE] |

*Osmotically acting laxatives*

## ▪ MACROGOL-3350

**Note** Pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 510 g and pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

***6170***

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**macrogol-3350 1 g/g powder for oral liquid, 510 g**

| 5426N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 3 | .. | *26.23 | 27.44 | [a] OsmoLax [KY] |

**macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets**

| 2351R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 3 | .. | *26.23 | 27.44 | [a] Herron ClearLax [ON] |

## ▪ MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE

**Authority required (STREAMLINED)**

***6171***

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets**

| 5389P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 3 | .. | *26.23 | 27.44 | [a] APO-MACROGOL plus ELECTROLYTES [TX]<br>[a] LaxaCon [EA]<br>[a] Macrovic [RF]<br>[a] Movicol [NE] | [a] Chemists' Own Macrogol with Electrolytes [RW]<br>[a] lax-sachets [AE]<br>[a] Molaxole [HM] |

**macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL**

| 10127B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 3 | .. | *21.17 | 22.38 | Movicol Liquid [NE] |

*Enemas*

## ▪ BISACODYL

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**bisacodyl 10 mg/5 mL enema, 25 x 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5302C NP | ‡1 | 3 | .. | 38.50 | 38.80 | Bisalax [AS] |

## ▪ SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5331N NP | 2 | 3 | .. | *29.35 | 30.56 | Micolette [AE] |

*Peripheral opioid receptor antagonists*

## ▪ METHYLNALTREXONE

**Authority required (STREAMLINED)**

***6180***

Opioid-induced constipation

**Clinical criteria:**

- The treatment must be in combination with oral laxatives, **AND**
- Patient must be receiving palliative care, **AND**
- Patient must have failed to respond to laxatives.

**METHYLNALTREXONE Solution for injection containing methylnaltrexone bromide 12 mg in 0.6 mL, 7**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5424L NP | 1 | .. | .. | 263.80 | 38.80 | Relistor [LM] |

**methylnaltrexone bromide 12 mg/0.6 mL injection, 0.6 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5423K NP | 7 | .. | .. | *263.77 | 38.80 | Relistor [LM] |

# ▪ MUSCULO-SKELETAL SYSTEM

# ▪ ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

## ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS

*Acetic acid derivatives and related substances*

## ▪ DICLOFENAC

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must be receiving palliative care.

**diclofenac sodium 100 mg suppository, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5363G NP | 2 | 3 | .. | *27.51 | 28.72 | Voltaren 100 [NV] |

**diclofenac sodium 50 mg enteric tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5362F NP | 1 | 3 | .. | 13.14 | 14.35 | [a] APO-Diclofenac [TX]<br>[a] Diclofenac Amneal [ED]<br>[a] Diclofenac Sandoz [SZ] | [a] Clonac 50 [RW]<br>[a] Diclofenac AN [EA]<br>[a] Fenac [AF] |
| | | | [B]3.46 | 16.60 | 14.35 | [a] Voltaren 50 [NV] | |

**diclofenac sodium 25 mg enteric tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5361E NP | 2 | 3 | .. | *14.03 | 15.24 | [a] APO-Diclofenac [TX]<br>[a] Diclofenac Amneal [ED]<br>[a] Diclofenac Sandoz [SZ] | [a] Clonac 25 [RW]<br>[a] Diclofenac AN [EA]<br>[a] Fenac 25 [AF] |
| | | | [B]3.44 | *17.47 | 15.24 | [a] Voltaren 25 [NV] | |

## ▪ INDOMETHACIN

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must be receiving palliative care.

**indomethacin 100 mg suppository, 20**

5378C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | .. | *25.07 | 26.28 | Indocid [AS] |

**indomethacin 25 mg capsule, 50**

5377B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | .. | *16.69 | 17.90 | [a] Arthrexin [AF] |
| | | [B]4.04 | *20.73 | 17.90 | [a] Indocid [AS] |

*Propionic acid derivatives*

## ▪ IBUPROFEN

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must be receiving palliative care.

**ibuprofen 400 mg tablet, 30**

5368M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 3 | .. | *16.84 | 18.05 | [a] APO-Ibuprofen 400 [TX] | [a] Brufen [GO] |

## ▪ NAPROXEN

**Restricted benefit**

Severe pain

**Treatment criteria:**

- Patient must be undergoing palliative care.

**Clinical criteria:**

- Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

**naproxen 125 mg/5 mL oral liquid, 474 mL**

5397C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 3 | .. | 121.27 | 38.80 | Phebra Naproxen Suspension [PL] |

## ▪ NAPROXEN

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must be receiving palliative care.

**naproxen 1 g modified release tablet, 28**

5348L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 17.65 | 18.86 | [a] Proxen SR 1000 [IY] |
| | | [B]1.12 | 18.77 | 18.86 | [a] Naprosyn SR1000 [IX] |

**naproxen 250 mg tablet, 50**

5345H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | .. | *18.35 | 19.56 | [a] Inza 250 [AF] |
| | | [B]2.24 | *20.59 | 19.56 | [a] Naprosyn [IX] |

**naproxen 750 mg modified release tablet, 28**

5347K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 16.01 | 17.22 | [a] Proxen SR 750 [IY] |
| | | [B]1.06 | 17.07 | 17.22 | [a] Naprosyn SR750 [IX] |

**naproxen 500 mg tablet, 50**

5346J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 16.46 | 17.67 | [a] Inza 500 [AF] |
| | | [B]1.12 | 17.58 | 17.67 | [a] Naprosyn [IX] |

## ▪ NAPROXEN

**Note** Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must be receiving palliative care.

**naproxen sodium 550 mg tablet, 50**

| 5353R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 3 | .. | 16.61 | 17.82 | [a] Crysanal [IY] |
| | | | [B]1.89 | 18.50 | 17.82 | [a] Anaprox 550 [IX] |



# NERVOUS SYSTEM

## ANALGESICS

### OPIOIDS

*Natural opium alkaloids*

### MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Telephone approvals are limited to 1 month's therapy.

**Authority required**

Chronic severe disabling pain

**Clinical criteria:**

- Patient must be receiving palliative care, **AND**
- The condition must be unresponsive to non-opioid analgesics.

**morphine sulfate 200 mg modified release tablet, 28**

| 5391R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 116.58 | 38.80 | MS Contin [MF] |

### MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Telephone approvals are limited to 1 month's therapy.

**Authority required**

Severe disabling pain

**Clinical criteria:**

- Patient must be receiving palliative care, **AND**
- The condition must be unresponsive to non-opioid analgesics.

**morphine sulfate 20 mg tablet, 20**

| 5394X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 19.43 | 20.64 | Sevredol [MF] |

**morphine sulfate 10 mg tablet, 20**

| 5393W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 18.61 | 19.82 | Sevredol [MF] |

*Phenylpiperidine derivatives*

### FENTANYL

**Caution** The risk of drug dependence is high.

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Breakthrough pain

Treatment Phase: Initial treatment for dose titration

**Clinical criteria:**

- Patient must have cancer, **AND**
- Patient must have pain directly attributable to cancer, **AND**
- Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
- Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR
- The treatment must be used as short acting opioids are considered clinically inappropriate; OR
- Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

**Treatment criteria:**

- Patient must be undergoing palliative care.

**fentanyl 300 microgram sublingual tablet, 10**

| 10606F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 87.21 | 38.80 | Abstral [FK] |

**fentanyl 400 microgram sublingual tablet, 10**

| 10603C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 87.21 | 38.80 | Abstral [FK] |

**fentanyl 600 microgram sublingual tablet, 10**

| 10604D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 87.21 | 38.80 | Abstral [FK] |

**FENTANYL Lozenge 600 micrograms (as citrate), 9**

| 5403J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 96.35 | 38.80 | Actiq [TB] |

**FENTANYL Lozenge 400 micrograms (as citrate), 9**

| 5402H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 96.35 | 38.80 | Actiq [TB] |

**FENTANYL Lozenge 200 micrograms (as citrate), 9**

| 5401G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 96.35 | 38.80 | Actiq [TB] |

**FENTANYL Lozenge 1600 micrograms (as citrate), 9**

| 5406M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 96.35 | 38.80 | Actiq [TB] |

**fentanyl 100 microgram sublingual tablet, 10**

| 10601Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 87.21 | 38.80 | Abstral [FK] |

**FENTANYL Lozenge 1200 micrograms (as citrate), 9**

| 5405L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 96.35 | 38.80 | Actiq [TB] |

**fentanyl 800 microgram sublingual tablet, 10**

| 10612M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 87.21 | 38.80 | Abstral [FK] |

**fentanyl 200 microgram sublingual tablet, 10**

| 10600X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 87.21 | 38.80 | Abstral [FK] |

**FENTANYL Lozenge 800 micrograms (as citrate), 9**

| 5404K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 96.35 | 38.80 | Actiq [TB] |

## ▪ FENTANYL

**Caution** The risk of drug dependence is high.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Breakthrough pain

Treatment Phase: Initial treatment for dose titration

**Clinical criteria:**

- Patient must have cancer, **AND**
- Patient must have pain directly attributable to cancer, **AND**
- Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
- Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR

- The treatment must be used as short acting opioids are considered clinically inappropriate; OR
- Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

**Treatment criteria:**

- Patient must be undergoing palliative care.

**fentanyl 100 microgram orally disintegrating tablet, 4**

| 10729Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *72.60 | 38.80 | Fentora [TB] |

**fentanyl 600 microgram orally disintegrating tablet, 4**

| 10722H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *72.60 | 38.80 | Fentora [TB] |

**fentanyl 400 microgram orally disintegrating tablet, 4**

| 10739F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *72.60 | 38.80 | Fentora [TB] |

**fentanyl 200 microgram orally disintegrating tablet, 4**

| 10697B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *72.60 | 38.80 | Fentora [TB] |

**fentanyl 800 microgram orally disintegrating tablet, 4**

| 10723J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *72.60 | 38.80 | Fentora [TB] |

## ▪ FENTANYL

**Caution** The risk of drug dependence is high.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** For first continuing supply, applications for increased repeats for up to 3 months' supply may be authorised.

**Note** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

**Note** Telephone approvals are limited to 1 months' therapy.

**Authority required**

Breakthrough pain

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have cancer, **AND**
- Patient must have pain directly attributable to cancer, **AND**
- Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
- Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR
- The treatment must be used as short acting opioids are considered clinically inappropriate; OR
- Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

**Treatment criteria:**

- Patient must be undergoing palliative care.

**FENTANYL Lozenge 600 micrograms (as citrate), 30**

| 5409Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *575.36 | 38.80 | Actiq [TB] |

**FENTANYL Lozenge 200 micrograms (as citrate), 30**

| 5407N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *575.36 | 38.80 | Actiq [TB] |

**fentanyl 400 microgram sublingual tablet, 30**

| 10608H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *461.84 | 38.80 | Abstral [FK] |

**FENTANYL Lozenge 400 micrograms (as citrate), 30**

| 5408P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *575.36 | 38.80 | Actiq [TB] |

**fentanyl 100 microgram sublingual tablet, 30**

| 10602B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *461.84 | 38.80 | Abstral [FK] |

**FENTANYL Lozenge 800 micrograms (as citrate), 30**

| 5410R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *575.36 | 38.80 | Actiq [TB] |

**fentanyl 300 microgram sublingual tablet, 30**

| 10610K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *461.84 | 38.80 | Abstral [FK] |

**fentanyl 200 microgram sublingual tablet, 30**

| 10607G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *461.84 | 38.80 | Abstral [FK] |

**FENTANYL Lozenge 1600 micrograms (as citrate), 30**

| 5412W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *575.36 | 38.80 | Actiq [TB] |

**fentanyl 600 microgram sublingual tablet, 30**

| 10613N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *461.84 | 38.80 | Abstral [FK] |

**fentanyl 800 microgram sublingual tablet, 30**

| 10611L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *461.84 | 38.80 | Abstral [FK] |

**FENTANYL Lozenge 1200 micrograms (as citrate), 30**

| 5411T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *575.36 | 38.80 | Actiq [TB] |

## ▪ FENTANYL

**Caution** The risk of drug dependence is high.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** For first continuing supply, applications for increased repeats for up to 3 months' supply may be authorised.

**Note** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

**Note** Telephone approvals are limited to 1 months' therapy.

**Authority required**

Breakthrough pain

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have cancer, **AND**
- Patient must have pain directly attributable to cancer, **AND**
- Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
- Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR
- The treatment must be used as short acting opioids are considered clinically inappropriate; OR
- Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

**Treatment criteria:**

- Patient must be undergoing palliative care.

**fentanyl 800 microgram orally disintegrating tablet, 28**

| 10738E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *431.58 | 38.80 | Fentora [TB] |

**fentanyl 600 microgram orally disintegrating tablet, 28**

| 10713W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *431.58 | 38.80 | Fentora [TB] |

**fentanyl 200 microgram orally disintegrating tablet, 28**

| 10698C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *431.58 | 38.80 | Fentora [TB] |

**fentanyl 100 microgram orally disintegrating tablet, 28**

| 10684H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *431.58 | 38.80 | Fentora [TB] |

**fentanyl 400 microgram orally disintegrating tablet, 28**

| 10737D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *431.58 | 38.80 | Fentora [TB] |

*Diphenylpropylamine derivatives*

## ▪ METHADONE

**Caution** The risk of drug dependence is high.

**Note** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

**Note** Telephone approvals are limited to 1 month's therapy.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Chronic severe disabling pain

Treatment Phase: Initial treatment, for up to 3 months

**Clinical criteria:**

- Patient must be receiving palliative care, **AND**
- The condition must be unresponsive to non-opioid analgesics.

**methadone hydrochloride 5 mg/mL oral liquid, 200 mL**

| 5399E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 22.60 | 23.81 | Aspen Methadone Syrup [QA] |

## ▪ METHADONE

**Caution** The risk of drug dependence is high.

**Note** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

**Note** Telephone approvals are limited to 1 month's therapy.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Chronic severe disabling pain

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must be receiving palliative care, **AND**
- The condition must be unresponsive to non-opioid analgesics.

**methadone hydrochloride 5 mg/mL oral liquid, 200 mL**

| 5400F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 22.60 | 23.81 | Aspen Methadone Syrup [QA] |

*Oripavine derivatives*

## ▪ BUPRENORPHINE

**Caution** The risk of drug dependence is high.

**Note** Telephone approvals are limited to 1 month's therapy.

**Authority required**

Chronic severe disabling pain

**Clinical criteria:**

- Patient must be receiving palliative care, **AND**
- The condition must be unresponsive to non-opioid analgesics.

**buprenorphine 15 microgram/hour patch, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10953L NP | 2 | 2 | .. | *80.56 | 38.80 | Norspan [MF] |

**buprenorphine 25 microgram/hour patch, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10964C NP | 2 | 2 | .. | *108.20 | 38.80 | Norspan [MF] |

**buprenorphine 10 microgram/hour patch, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10948F NP | 2 | 2 | .. | *66.38 | 38.80 | Norspan [MF] |

**buprenorphine 40 microgram/hour patch, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10959T NP | 2 | 2 | .. | *148.52 | 38.80 | Norspan [MF] |

**buprenorphine 5 microgram/hour patch, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10957Q NP | 2 | 2 | .. | *43.14 | 38.80 | Norspan [MF] |

**buprenorphine 30 microgram/hour patch, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10949G NP | 2 | 2 | .. | *121.64 | 38.80 | Norspan [MF] |

**buprenorphine 20 microgram/hour patch, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10970J NP | 2 | 2 | .. | *94.76 | 38.80 | Norspan [MF] |

## OTHER ANALGESICS AND ANTIPYRETICS

*Anilides*

### ▪ PARACETAMOL

**Restricted benefit**

Analgesia or fever

**Clinical criteria:**

- Patient must be receiving palliative care, **AND**
- Patient must be intolerant to alternative therapy.

**paracetamol 500 mg suppository, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5319Y NP | 4 | 3 | .. | *82.07 | 38.80 | Panadol [GC] |

### ▪ PARACETAMOL

**Note** Pharmaceutical benefits that have the form paracetamol 665 mg tablet: modified release, 96 and pharmaceutical benefits that have the form paracetamol 665 mg tablet: modified release, 192 are equivalent for the purposes of substitution.

**Restricted benefit**

Analgesia or fever

**Clinical criteria:**

- Patient must be receiving palliative care, **AND**
- Patient must be intolerant to alternative therapy.

**paracetamol 665 mg modified release tablet, 96**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5343F NP | 2 | 3 | .. | *18.55 | 19.76 | [a] APOHEALTH Osteo Relief Paracetamol 665 mg [TX] | [a] Osteomol 665 Paracetamol [CR] |

**paracetamol 665 mg tablet: modified release, 192**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10796F NP | 1 | 3 | .. | 18.55 | 19.76 | [a] Osteomol 665 Paracetamol [CR] |

# ▪ ANTIEPILEPTICS

## ANTIEPILEPTICS

*Benzodiazepine derivatives*

## ▪ CLONAZEPAM

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Myoclonus

**Clinical criteria:**

- The treatment must be for prophylaxis or prevention of the indication, **AND**
- Patient must be receiving palliative care.

**clonazepam 500 microgram tablet, 100**

| 5337X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 3 | .. | 16.78 | 17.99 | [a] Paxam 0.5 [AF] |
| | | | [B]1.84 | 18.62 | 17.99 | [a] Rivotril [RO] |

**clonazepam 2 mg tablet, 100**

| 5338Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 3 | .. | 21.80 | 23.01 | [a] Paxam 2 [AF] |
| | | | [B]2.30 | 24.10 | 23.01 | [a] Rivotril [RO] |

**clonazepam 2.5 mg/mL oral liquid, 10 mL**

| 5339B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 3 | .. | *18.59 | 19.80 | Rivotril [RO] |

# ▪ PSYCHOLEPTICS

## ANXIOLYTICS

*Benzodiazepine derivatives*

## ▪ DIAZEPAM

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Anxiety

**Clinical criteria:**

- Patient must be receiving palliative care.

**diazepam 2 mg tablet, 50**

| 5355W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | .. | 12.41 | 13.62 | [a] Antenex 2 [AF]<br>[a] Valpam 2 [RW] | [a] APO-Diazepam [TX] |

**diazepam 5 mg tablet, 50**

| 5356X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | .. | 12.48 | 13.69 | [a] Antenex 5 [AF]<br>[a] Ranzepam [RA] | [a] APO-Diazepam [TX]<br>[a] Valpam 5 [RW] |
| | | | [B]2.19 | 14.67 | 13.69 | [a] Valium [RO] | |

## ▪ OXAZEPAM

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Anxiety

**Clinical criteria:**

- Patient must be receiving palliative care.

**oxazepam 30 mg tablet, 25**

| 5372R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 3 | .. | *13.25 | 14.46 | [a] Alepam 30 [AF]<br>[a] Murelax [RW] | [a] APO-Oxazepam [TX] |
| | | | [B]4.66 | *17.91 | 14.46 | [a] Serepax [QA] | |

**oxazepam 15 mg tablet, 25**

| 5371Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 3 | .. | *13.93 | 15.14 | [a] Alepam 15 [AF] |
| | | | [B]5.32 | *19.25 | 15.14 | [a] Serepax [QA] |

## HYPNOTICS AND SEDATIVES

*Benzodiazepine derivatives*

## ▪ NITRAZEPAM

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Insomnia

**Clinical criteria:**

- Patient must be receiving palliative care.

**nitrazepam 5 mg tablet, 25**

5359C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | .. | *14.31 | 15.52 | [a] Alodorm [AF] |
| | | [B]2.48 | *16.79 | 15.52 | [a] Mogadon [IA] |

## ▪ TEMAZEPAM

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Insomnia

**Clinical criteria:**

- Patient must be receiving palliative care.

**temazepam 10 mg tablet, 25**

5375X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 3 | .. | *13.25 | 14.46 | [a] APO-Temazepam [TX]<br>[a] Temtabs [FM] | [a] Temaze [AF] |
| | | [B]6.96 | *20.21 | 14.46 | [a] Normison [QA] | |

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# BLOOD AND BLOOD FORMING ORGANS

## ANTIHEMORRHAGICS

### VITAMIN K AND OTHER HEMOSTATICS

*Other systemic hemostatics*



### ELTROMBOPAG

**Note** No applications for increased repeats will be authorised.

**Authority required**

Severe thrombocytopenia

Treatment Phase: Initial treatment 1 - New patient

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have had a splenectomy, **AND**
- Patient must have failed to acheive an adequate response to, or be intolerant to, corticosteroid therapy following the splenectomy, **AND**
- Patient must have failed to acheive an adequate response to, or be intolerant to, immunoglobulin therapy following the splenectomy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**

- Patient must be an adult.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,

(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and

(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

**Note** Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Authority required**

Severe thrombocytopenia

Treatment Phase: Initial treatment 2 - New patient

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must not have had a splenectomy, **AND**
- Patient must have failed to acheive an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks, **AND**
- Patient must have failed to acheive an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- Patient must be unsuitable for splenectomy due to medical reasons, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**

- Patient must be an adult.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,

(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and

(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

**Note** Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

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**Authority required**

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted treatment

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**

- Patient must be an adult.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised treatment with this drug,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the First continuing PBS-subsidised treatment or Re-initiation of interrupted PBS-subsidised treatment must be made in writing and must include:

(1) a completed authority prescription form, and

(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form , and

(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The platelet count must be no more than one month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

**Note** Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe thrombocytopenia

Treatment Phase: Second or subsequent Continuing treatment

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a continuing response to treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**

- Patient must be an adult.

For the purpose of this restriction, a continuing response to treatment with drug is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with this drug

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

The platelet count must be no more than one month old at the time of application.

Authority applications for second and subsequent periods of continuing therapy may be made by telephone

**Note** Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

**Note** Authority applications for second and subsequent continuing treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Authority required**

Severe thrombocytopenia

Treatment Phase: Initial 1, Initial 2, First Continuing treatment or Re-initiation of interrupted treatment, and Second and Subsequent Continuing treatment - balance of supply

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second and subsequent Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**

- Patient must be an adult.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**eltrombopag 25 mg tablet, 28**

| 5827Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 5 | .. | 1483.55 | Revolade [NV] |

**eltrombopag 50 mg tablet, 28**

| 5828R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 5 | .. | 2919.95 | Revolade [NV] |

## ▪ ROMIPLOSTIM

**Authority required**

Severe thrombocytopenia

Treatment Phase: Initial treatment 1 - New patient

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have had a splenectomy, **AND**
- Patient must have failed to acheive an adequate response to, or be intolerant to, corticosteroid therapy following the splenectomy, **AND**
- Patient must have failed to acheive an adequate response to, or be intolerant to, immunoglobulin therapy following the splenectomy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**

- Patient must be an adult.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be requested by telephone. The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,

(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and

(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

**Note** Romiplostim is not PBS-subsidised as an alternative to splenectomy.

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe this drug should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe thrombocytopenia

Treatment Phase: Initial treatment 2 - New patient

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must not have had a splenectomy, **AND**
- Patient must have failed to acheive an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks, **AND**
- Patient must have failed to acheive an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- Patient must be unsuitable for splenectomy due to medical reasons, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**

- Patient must be an adult.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be requested by telephone. The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,

(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and

(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

**Note** Romiplostim is not PBS-subsidised as an alternative to splenectomy.

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe this drug should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted treatment

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**

- Patient must be an adult.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised treatment with this drug,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

Applications for the First continuing PBS-subsidised treatment or Re-initiation of interrupted PBS-subsidised treatment must be made in writing and must include:

(1) a completed authority prescription form, and

(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form , and

(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The platelet count must be no more than one month old at the time of application.

**Note** Romiplostim is not PBS-subsidised as an alternative to splenectomy.

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe this drug should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a continuing response to treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**

- Patient must be an adult.

For the purpose of this restriction, a continuing response to treatment with drug is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with this drug

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

The platelet count must be no more than one month old at the time of application.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

Authority applications for second and subsequent periods of continuing therapy may be made by telephone

**Note** Romiplostim is not PBS-subsidised as an alternative to splenectomy.

**Note** Authority applications for second and subsequent continuing treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe this drug should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe thrombocytopenia

Treatment Phase: Initial 1, Initial 2, First Continuing treatment or Re-initiation of interrupted treatment, and Second and Subsequent Continuing treatment - balance of supply

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second and subsequent Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**

- Patient must be an adult.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No applications for increased repeats will be authorised.

**romiplostim 500 microgram injection, 1 vial**

9699L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 1904.40 | Nplate [AN] |

**romiplostim 250 microgram injection, 1 vial**

9697J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 972.93 | Nplate [AN] |

## ANTIANEMIC PREPARATIONS

### OTHER ANTIANEMIC PREPARATIONS

*Other antianemic preparations*

## ▪ DARBEPOETIN ALFA

**Authority required**

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**darbepoetin alfa 150 microgram/0.3 mL injection, 0.3 mL syringe**

| 6493R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 8 | 5 | .. | *3756.43 | Aranesp SureClick [AN] |

**darbepoetin alfa 100 microgram/0.5 mL injection, 0.5 mL syringe**

| 6492Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 8 | 5 | .. | *2536.59 | Aranesp SureClick [AN] |

**darbepoetin alfa 150 microgram/0.3 mL injection, 4 x 0.3 mL syringes**

| 6365B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *3756.43 | Aranesp [AN] |

**darbepoetin alfa 50 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

| 6324W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1355.09 | Aranesp [AN] |

**darbepoetin alfa 100 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

| 6326Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *2536.63 | Aranesp [AN] |

**darbepoetin alfa 60 microgram/0.3 mL injection, 0.3 mL syringe**

| 6490N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 8 | 5 | .. | *1582.99 | Aranesp SureClick [AN] |

**darbepoetin alfa 40 microgram/0.4 mL injection, 0.4 mL syringe**

| 6489M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 8 | 5 | .. | *1105.07 | Aranesp SureClick [AN] |

**darbepoetin alfa 20 microgram/0.5 mL injection, 0.5 mL syringe**

| 6488L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 8 | 5 | .. | *669.79 | Aranesp SureClick [AN] |

**darbepoetin alfa 20 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

| 6321Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *669.71 | Aranesp [AN] |

**darbepoetin alfa 30 microgram/0.3 mL injection, 4 x 0.3 mL syringes**

| 6322R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *913.59 | Aranesp [AN] |

**darbepoetin alfa 60 microgram/0.3 mL injection, 4 x 0.3 mL syringes**

| 6325X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1582.97 | Aranesp [AN] |

**darbepoetin alfa 40 microgram/0.4 mL injection, 4 x 0.4 mL syringes**

| 6323T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1105.07 | Aranesp [AN] |

**darbepoetin alfa 80 microgram/0.4 mL injection, 0.4 mL syringe**

| 6491P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 8 | 5 | .. | *2068.75 | Aranesp SureClick [AN] |

**darbepoetin alfa 10 microgram/0.4 mL injection, 4 x 0.4 mL syringes**

| 6320P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *358.97 | Aranesp [AN] |

**darbepoetin alfa 80 microgram/0.4 mL injection, 4 x 0.4 mL syringes**

| 6438W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *2068.75 | Aranesp [AN] |

## ▪ EPOETIN ALFA

**Authority required**

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**epoetin alfa 1000 units/0.5 mL injection, 6 x 0.5 mL syringes**

| 6251B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *283.11 | Eprex 1000 [JC] |

**epoetin alfa 4000 units/0.4 mL injection, 6 x 0.4 mL syringes**

| 6206P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *846.27 | Eprex 4000 [JC] |

**epoetin alfa 3000 units/0.3 mL injection, 6 x 0.3 mL syringes**

| 6205N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *666.05 | Eprex 3000 [JC] |

**epoetin alfa 2000 units/0.5 mL injection, 6 x 0.5 mL syringes**

| 6204M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *517.75 | Eprex 2000 [JC] |

**epoetin alfa 6000 units/0.6 mL injection, 6 x 0.6 mL syringes**

| 6303R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1239.53 | Eprex 6000 [JC] |

**epoetin alfa 8000 units/0.8 mL injection, 6 x 0.8 mL syringes**

| 6305W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1593.67 | Eprex 8000 [JC] |

**epoetin alfa 20 000 units/0.5 mL injection, 6 x 0.5 mL syringes**

| 6434P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *3729.35 | Eprex 20,000 [JC] |

**epoetin alfa 10 000 units/mL injection, 6 x 1 mL syringes**

| 6207Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1918.93 | Eprex 10000 [JC] |

**epoetin alfa 5000 units/0.5 mL injection, 6 x 0.5 mL syringes**

| 6302Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1051.63 | Eprex 5000 [JC] |

**epoetin alfa 40 000 units/mL injection, 1 mL syringe**

| 6339P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1238.45 | Eprex 40,000 [JC] |

## ▪ EPOETIN BETA

**Authority required**

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**epoetin beta 10 000 units/0.6 mL injection, 6 x 0.6 mL syringes**

| 6485H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1918.93 | NeoRecormon [RO] |

**epoetin beta 3000 units/0.3 mL injection, 6 x 0.3 mL syringes**

| 6481D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *666.05 | NeoRecormon [RO] |

**epoetin beta 4000 units/0.3 mL injection, 6 x 0.3 mL syringes**

| 6482E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *846.27 | NeoRecormon [RO] |

**epoetin beta 5000 units/0.3 mL injection, 6 x 0.3 mL syringes**

| 6483F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1051.65 | NeoRecormon [RO] |

**epoetin beta 6000 units/0.3 mL injection, 6 x 0.3 mL syringes**

| 6484G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1239.53 | NeoRecormon [RO] |

**epoetin beta 2000 units/0.3 mL injection, 6 x 0.3 mL syringes**

| 6480C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *517.75 | NeoRecormon [RO] |

## ▪ EPOETIN LAMBDA

**Note** Epoetin lambda should only be administered by the intravenous route.

**Authority required**

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**epoetin lambda 8000 units/0.8 mL injection, 6 x 0.8 mL syringes**

| 9593X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1512.27 | Novicrit [SZ] |

**epoetin lambda 2000 units/mL injection, 6 x 1 mL syringes**

| 9686T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *490.87 | Novicrit [SZ] |

**epoetin lambda 1000 units/0.5 mL injection, 6 x 0.5 mL syringes**

| 9685R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *268.59 | Novicrit [SZ] |

**epoetin lambda 3000 units/0.3 mL injection, 6 x 0.3 mL syringes**

| 9687W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *631.37 | Novicrit [SZ] |

**epoetin lambda 5000 units/0.5 mL injection, 6 x 0.5 mL syringes**

| 9588P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *996.83 | Novicrit [SZ] |

**epoetin lambda 6000 units/0.6 mL injection, 6 x 0.6 mL syringes**

| 9590R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1176.77 | Novicrit [SZ] |

**epoetin lambda 10 000 units/mL injection, 6 x 1 mL syringes**

| 9595B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1820.43 | Novicrit [SZ] |

**epoetin lambda 4000 units/0.4 mL injection, 6 x 0.4 mL syringes**

| 9688X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *802.11 | Novicrit [SZ] |

## ▪ METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA

**Authority required**

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**methoxy polyethylene glycol-epoetin beta 360 microgram/0.6 mL injection, 1 x 0.6 mL syringe**

| 9580F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *3207.35 | Mircera [RO] |

**methoxy polyethylene glycol-epoetin beta 50 microgram/0.3 mL injection, 1 x 0.3 mL syringe**

| 9575Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *615.07 | Mircera [RO] |

**methoxy polyethylene glycol-epoetin beta 120 microgram/0.3 mL injection, 1 x 0.3 mL syringe**

| 9578D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1321.71 | Mircera [RO] |

**methoxy polyethylene glycol-epoetin beta 30 microgram/0.3 mL injection, 1 x 0.3 mL syringe**

| 9574X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *371.89 | Mircera [RO] |

**methoxy polyethylene glycol-epoetin beta 75 microgram/0.3 mL injection, 1 x 0.3 mL syringe**

| 9576B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *892.41 | Mircera [RO] |

**methoxy polyethylene glycol-epoetin beta 100 microgram/0.3 mL injection, 1 x 0.3 mL syringe**

| 9577C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1148.03 | Mircera [RO] |

**methoxy polyethylene glycol-epoetin beta 200 microgram/0.3 mL injection, 1 x 0.3 mL syringe**

| 9579E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1875.23 | Mircera [RO] |



# CARDIOVASCULAR SYSTEM

## ANTIHYPERTENSIVES

### OTHER ANTIHYPERTENSIVES

*Antihypertensives for pulmonary arterial hypertension*

### AMBRISENTAN

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease,

**AND**

- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001



**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**ambrisentan 10 mg tablet, 30**

9649W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 2779.80 | Volibris [GK] |

**ambrisentan 5 mg tablet, 30**

9648T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 2779.80 | Volibris [GK] |

## ▪ BOSENTAN

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.
The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.
The approved second authority prescription will be returned to the prescriber by the Department of Human Services two

weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.



**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.



**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**bosentan 125 mg tablet, 60**

6430K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 2342.58 | [a] APO-BOSENTAN [GX] | [a] Bosentan APOTEX [TX] |
| | | | | [a] BOSENTAN-DRLA [RZ] | [a] Bosentan GH [GQ] |
| | | | | [a] Bosentan Mylan [AF] | [a] Bosentan RBX [RA] |
| | | | | [a] Bosentan Sandoz [SZ] | [a] BOSLEER [RW] |
| | | | | [a] Tracleer [AT] | |

## ▪ BOSENTAN

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.
The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.
The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.
The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**

- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.



**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Cessation of treatment (all patients)

**Clinical criteria:**

- Patient must have received approval for initial PBS-subsidised treatment with this agent, **AND**
- Patient must have not responded to prior PBS-subsidised therapy with this agent, **AND**
- The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**bosentan 62.5 mg tablet, 60**

6429J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 2342.58 | [a] APO-BOSENTAN [GX] | [a] Bosentan APOTEX [TX] |
| | | | | [a] BOSENTAN-DRLA [RZ] | [a] Bosentan Mylan [AF] |
| | | | | [a] Bosentan RBX [RA] | [a] Bosentan Sandoz [SZ] |
| | | | | [a] BOSLEER [RW] | [a] Tracleer [AT] |

## ▪ EPOPROSTENOL

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and

(4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients) or Initial 2 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**

- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.



**epoprostenol 1.5 mg injection [1 vial] (&) inert substance diluent [2 x 50 mL vials], 1 pack**

| 11082G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 77.70 | Flolan [GK] |

**epoprostenol 1.5 mg injection, 1 vial**

| 10129D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 77.70 | Veletri [AT] |

**epoprostenol 500 microgram injection, 1 vial**

| 10111E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 43.76 | Veletri [AT] |

**epoprostenol 500 microgram injection [1 vial] (&) inert substance diluent [2 x 50 mL vials], 1 pack**

| 11069N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 43.76 | Flolan [GK] |

## ▪ ILOPROST

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with this agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III drug-induced PAH, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III drug-induced PAH and a mean right atrial pressure greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III drug-induced PAH with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class IV drug-induced PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
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HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or drug-induced PAH and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and

(4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Note** Special Pricing Arrangements apply.

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**

- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

HSD (Private)

**iloprost 20 microgram/2 mL inhalation solution, 30 x 2 mL ampoules**

6456T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 432.39 | Ventavis [BN] |

## ▪ MACITENTAN

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
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HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

A maximum of 5 repeats will be authorised.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**

- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.



**macitentan 10 mg tablet, 30**

10134J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 2923.62 | Opsumit [AT] |

## ▪ RIOCIGUAT

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 1 month following cessation of therapy, as recommended by the TGA-approved Product Information.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have WHO Functional Class II, III or IV CTEPH, **AND**
- The condition must be inoperable by pulmonary endarterectomy; OR
- The condition must be recurrent or persistent following pulmonary endarterectomy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated in a centre with expertise in the management of CTEPH.

**Population criteria:**

- Patient must be aged 18 years or older.

CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:

- Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn*sec*$cm^{-5}$ measured at least 90 days after start of full anticoagulation; and
- A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.

CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:

- RHC demonstrating a PVR of greater than 300 dyn*sec*$cm^{-5}$ measured at least 180 days following pulmonary endarterectomy.

Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be provided at the time of application.

Applications for authorisation must be in writing and must include:(1) completed authority prescription forms sufficient for dose titration; and(2) a completed CTEPH PBS Initial Authority Application - Supporting Information form which includes results from the 3 tests below, to establish baseline measurements, where available:(i) RHC composite assessment, and(ii) ECHO composite assessment, and(iii) 6 Minute Walk Test (6MWT); and(3) a signed patient acknowledgment form; and(4) confirmation of evidence of inoperable CTEPH including results of a pulmonary vascular resistance (PVR), a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or(5) confirmation of evidence of recurrent or persistent CTEPH including result of PVR and the date that pulmonary endarterectomy was performed; or(6) confirmation of an echocardiogram demonstrating right ventricular dysfunction.

Where it is not possible to perform all 3 tests above on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:(1) RHC plus ECHO composite assessments;(2) RHC composite assessment plus 6MWT;(3) RHC composite assessment only.

In circumstance where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:(1) ECHO composite assessment plus 6MWT;(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Prescriptions for dose titration must provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, The quantity approved must be based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 3 repeats.

The assessment of the patient's response to the initial 20-week course of treatment should be made following the preceding 16 weeks of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must demonstrate stable or responding disease, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated in a centre with expertise in the management of CTEPH.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be in writing and must include:(1) a completed authority prescription form; and(2) a completed CTEPH PBS Continuing Authority Application - Supporting Information form which includes results from the three tests below, where available:(i) RHC composite assessment; and(ii) ECHO composite assessment; and(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to this drug is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease.

The assessment of the patient's response to the continuing 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

The maximum quantity per prescription must be based on the dosage recommendations in the TGA-approved Product Information and be limited to provide sufficient supply for 1 month of treatment.

A maximum of 5 repeats will be authorised.

Applications for continuing treatment with this drug should be made two weeks prior to the completion of the 6-month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate disease stability or improvement to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Grandfathered patients

**Clinical criteria:**

- Patient must have previously received treatment with this drug for this condition prior to 1 January 2017, **AND**
- Patient must have a documented history of WHO Functional Class II, III or IV CTEPH, **AND**
- The condition must be inoperable by pulmonary endarterectomy; OR
- The condition must be recurrent or persistent following pulmonary endarterectomy.

**Treatment criteria:**

- Must be treated in a centre with expertise in the management of CTEPH.

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised agent for this condition.

**Population criteria:**

- Patient must be aged 18 years or older.

CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:

- Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn*sec*$cm^{-5}$ measured at least 90 days after start of full anticoagulation; and
- A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.

CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:

- RHC demonstrating a PVR of greater than 300 dyn*sec*$cm^{-5}$ measured at least 180 days following pulmonary endarterectomy.

Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be provided at the time of application.

Applications for authorisation must be in writing and must include:(1) A completed authority prescription form; and(2) a completed CTEPH PBS Initial Authority Application - Supporting Information form which includes results from the 3 tests below, to establish baseline measurements, where available:(i) RHC composite assessment, and(ii) ECHO composite assessment, and(iii) 6 Minute Walk Test (6MWT); and(3) a signed patient acknowledgment form; and(4) confirmation of evidence of inoperable CTEPH including results of a pulmonary vascular resistance (PVR), a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or(5) confirmation of evidence of recurrent or persistent CTEPH including result of PVR and the date that pulmonary endarterectomy was performed; or(6) confirmation of an echocardiogram demonstrating right ventricular dysfunction.

Where it is not possible to perform all 3 tests above on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:(1) RHC plus ECHO composite assessments;(2) RHC composite assessment plus 6MWT;(2) RHC composite assessment only.

In circumstance where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:(1) ECHO composite assessment plus 6MWT;(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial treatment restriction to complete a maximum of 20 weeks of treatment; OR
- Patient must have received insufficient therapy with this agent under the Continuing treatment restriction to complete a maximum of 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this agent under the Grandfathering restriction to complete a maximum of 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 20 or 24 weeks of treatment available under the above respective restriction, **AND**
- The treatment must be the sole PBS-subsidised agent for this condition.

**Treatment criteria:**

- Must be treated in a centre with expertise in the management of CTEPH.

**Population criteria:**

- Patient must be aged 18 years or older.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au



**riociguat 2 mg tablet, 84**

| 11017W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 3482.57 | Adempas [BN] |

**riociguat 1 mg tablet, 84**

| 11010L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 3482.57 | Adempas [BN] |

**riociguat 1 mg tablet, 42**

| 10990K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 1764.86 | Adempas [BN] |

**riociguat 500 microgram tablet, 84**

| 11008J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 3482.57 | Adempas [BN] |

**riociguat 1.5 mg tablet, 84**

| 10975P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 3482.57 | Adempas [BN] |

**riociguat 2 mg tablet, 42**

| 11012N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 1764.86 | Adempas [BN] |

**riociguat 2.5 mg tablet, 84**

| 11018X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 3482.57 | Adempas [BN] |

**riociguat 2.5 mg tablet, 42**

| 10985E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 1764.86 | Adempas [BN] |

**riociguat 500 microgram tablet, 42**

| 11009K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 1764.86 | Adempas [BN] |

**riociguat 1.5 mg tablet, 42**

| 10974N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 1764.86 | Adempas [BN] |

## ▪ RIOCIGUAT

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 1 month following cessation of therapy, as recommended by the TGA-approved Product Information.

**Note** Special Pricing Arrangements apply.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**

- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed Pulmonary Arterial Hypertension Initial PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed Pulmonary Arterial Hypertension Initial PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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HOBART TAS 7001

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).



**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made two weeks prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 4 (Grandfathered patients)

**Clinical criteria:**

- Patient must have previously received treatment with this drug for this condition prior to 1 February 2017, **AND**
- Patient must be receiving treatment with this drug at the time of application, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have a documented history of WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have a documented history of WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a documented history of a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have a documented history of right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have a documented history of failure to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. The test results provided must not be more than 2 months old at the time of application.Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite

assessments;(2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approval for authority prescriptions will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 5 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
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**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Note** No applications for increased repeats will be authorised.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 5 (Grandfathered patients)

**Clinical criteria:**

- Patient must have previously received treatment with this drug for this condition prior to 1 February 2017, **AND**
- Patient must be receiving treatment with this drug at the time of application, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have a documented history of WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have a documented history of WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have a documented history of WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have a documented history of WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have a documented history of WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have a documented history of WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have a documented history of WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. The test results provided must not be more than 2 months old at the time of application.Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments;(2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Approval for authority prescriptions will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 5 repeats.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Note** No applications for increased repeats will be authorised.

**riociguat 2 mg tablet, 84**

| 11030M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 3482.57 | Adempas [BN] |

**riociguat 1 mg tablet, 84**

| 11060D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 3482.57 | Adempas [BN] |

**riociguat 1 mg tablet, 42**

| 11028K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 1764.86 | Adempas [BN] |

**riociguat 500 microgram tablet, 84**

| 11058B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 3482.57 | Adempas [BN] |

**riociguat 1.5 mg tablet, 84**

| 11061E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 3482.57 | Adempas [BN] |

**riociguat 2 mg tablet, 42**

| 11045H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 1764.86 | Adempas [BN] |

**riociguat 2.5 mg tablet, 84**

| 11035T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 3482.57 | Adempas [BN] |

**riociguat 2.5 mg tablet, 42**

| 11052Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 1764.86 | Adempas [BN] |

**riociguat 500 microgram tablet, 42**

| 11031N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 1764.86 | Adempas [BN] |

**riociguat 1.5 mg tablet, 42**

| 11046J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 1764.86 | Adempas [BN] |

HSD (Private)

## ▪ SILDENAFIL

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to

connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
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HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.



**sildenafil 20 mg tablet, 90**

9605M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 339.66 | [a] APO-Sildenafil PHT [TX] | [a] Revatio [PF] |
| | | | | [a] Sildenafil AN PHT 20 [EA] | [a] SILDENAFIL-DRx [RZ] |
| | | | | [a] Sildenafil Sandoz PHT 20 [SZ] | |

## ▪ TADALAFIL

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

---

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**tadalafil 20 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1304P | 1 | .. | .. | 835.61 | Adcirca [LY] |

# SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

## PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

### ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES

*Other anterior pituitary lobe hormones and analogues*



## PEGVISOMANT

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

**Authority required**

Acromegaly

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than 1.3 times upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.

Somatostatin analogues include octreotide, lanreotide and pasireotide

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

1) Growth hormone level greater than 2.5 mcg/L; and

2) IGF-1 level is greater than 1.3 times the age- and sex-adjusted ULN

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

The authority application must be made in writing and must include:

a) two completed authority prescription forms ; and

b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and

c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and

d) a recent result of the IGF-1 level and the date of assessment ; and

e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide

No increase in the maximum quantity or number of units may be authorised for the loading dose.

**pegvisomant 20 mg injection [1 vial] (&) inert substance diluent [1 syringe], 1 pack**

| 11166Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 4 | .. | .. | *586.59 | Somavert [PF] |

## ▪ PEGVISOMANT

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Acromegaly

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than 1.3 times upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.

Somatostatin analogues include octreotide, lanreotide and pasireotide

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

1) Growth hormone level greater than 2.5 mcg/L; and

2) IGF-1 level is greater than 1.3 times the age- and sex-adjusted ULN

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

The authority application must be made in writing and must include:

a) two completed authority prescription forms ; and

b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and

c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and

d) a recent result of the IGF-1 level and the date of assessment ; and

e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide

No increase in the maximum quantity or number of units may be authorised for the loading dose.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Acromegaly

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition., **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue, **AND**
- The treatment must cease if IGF-1 is not lower after 3 months of pegvisomant treatment at the maximum tolerated dose.

Somatostatin analogues include octreotide, lanreotide and pasireotide

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of IGF-1 level taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of application.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Acromegaly

Treatment Phase: Grandfathering

**Clinical criteria:**

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 September 2017, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue, **AND**
- Patient must have had a documented age- and sex- adjusted insulin- like factor 1 (IGF-1) concentration greater than 1.3 times upper limit of normal (ULN) prior to commencing non- PBS- subsidised treatment with this drug.

Somatostatin analogues include octreotide, lanreotide and pasireotide

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Treatment must be ceased if IGF-1 level is not lower after 3 months of pegvisomant treatment at the maximum tolerated dose.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Acromegaly Pegvisomant Grandfather PBS Authority Application - Supporting Information Form; and
3. in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and
4. a recent result of the IGF-1 level and the date of assessment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**pegvisomant 10 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack**

| 11167R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 5 | .. | 4225.72 | Somavert [PF] |

**pegvisomant 15 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack**

| 11172B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 5 | .. | 4225.72 | Somavert [PF] |

**pegvisomant 20 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack**

| 11174D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 5 | .. | 4225.72 | Somavert [PF] |

## HYPOTHALAMIC HORMONES

*Somatostatin and analogues*

### ▪ LANREOTIDE

**Authority required**

Acromegaly

**Clinical criteria:**

- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; OR
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose), **AND**

- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

**lanreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack**

| 6332G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 11 | .. | *1472.15 | Somatuline LA [IS] |

## ▪ LANREOTIDE

**Authority required**

Acromegaly

**Clinical criteria:**

- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; OR
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

**Authority required**

Functional carcinoid tumour

**Clinical criteria:**

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe**

| 6425E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *4303.15 | Somatuline Autogel [IS] |

**lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe**

| 6424D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *3448.15 | Somatuline Autogel [IS] |

**lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe**

| 6423C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *2602.65 | Somatuline Autogel [IS] |

## ▪ OCTREOTIDE

**Authority required**

Acromegaly

**Clinical criteria:**

- The condition must be controlled with octreotide immediate release injections, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

**Authority required**

Functional carcinoid tumour

**Clinical criteria:**

- Patient must have achieved symptom control on octreotide immediate release injections, **AND**

- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**Authority required**

Vasoactive intestinal peptide secreting tumour (VIPoma)

**Clinical criteria:**

- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.



**octreotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

10549F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 5 | .. | *3526.77 | Sandostatin LAR [NV] |

**octreotide 10 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

10566D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 5 | .. | *2660.87 | Sandostatin LAR [NV] |

**octreotide 30 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

10558Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 5 | .. | *4402.07 | Sandostatin LAR [NV] |

## ▪ OCTREOTIDE

**Authority required**

Acromegaly

**Clinical criteria:**

- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; OR
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks, **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

**Authority required**

Functional carcinoid tumour

**Clinical criteria:**

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**Authority required**

Vasoactive intestinal peptide secreting tumour (VIPoma)

**Clinical criteria:**

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**octreotide 50 microgram/mL injection, 5 x 1 mL ampoules**

| 6227R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 18 | 11 | .. | *651.01 | [a] Hospira Pty Limited [PF]<br>[a] Octreotide (SUN) [RA] | [a] Octreotide MaxRx [GQ]<br>[a] Sandostatin 0.05 [NV] |

**octreotide 500 microgram/mL injection, 5 x 1 mL ampoules**

| 6229W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 18 | 11 | .. | *6241.63 | [a] Hospira Pty Limited [PF]<br>[a] Octreotide (SUN) [RA] | [a] Octreotide MaxRx [GQ]<br>[a] Sandostatin 0.5 [NV] |

**octreotide 100 microgram/mL injection, 5 x 1 mL ampoules**

| 6228T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 18 | 11 | .. | *1283.53 | [a] Hospira Pty Limited [PF]<br>[a] Octreotide (SUN) [RA] | [a] Octreotide MaxRx [GQ]<br>[a] Sandostatin 0.1 [NV] |

HSD (Private)

## ▪ PASIREOTIDE

**Caution** Careful monitoring of patients is mandatory due to high risk of developing hyperglycaemia

**Note** Special Pricing Arrangements apply.

**Authority required**

Acromegaly

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a mean growth hormone (GH) level greater than 2.5 micrograms per litre, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) level greater than 1.3 times the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

**Population criteria:**

- Patient must be aged 18 years or older.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

Failure to achieve biochemical control is defined as:

1) Growth hormone level is greater than 2.5 mcg/L; and

2) IGF-1 level is greater than 1.3 times the age- and sex-adjusted ULN

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

1) Growth hormone (GH) levels of less than 2.5 mcg/L; and

2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

The authority application must be made in writing and must include:

a) a completed authority prescription form; and

b) a completed Acromegaly PBS Authority Application - Supporting Information Form; and

c) a signed patient acknowledgment; and

d) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided; and

e) a recent copy of GH and IGF-1 levels must be provided.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Acromegaly

Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- Patient must have received non-PBS treatment with this drug for this condition prior to 1 September 2016.

**Population criteria:**

- Patient must be aged 18 years or older.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

1) Growth hormone (GH) levels of less than 2.5 mcg/L; and

2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

The authority application must be made in writing and must include:

a) a completed authority prescription form; and

b) a completed Acromegaly PBS Authority Application - Supporting Information Form; and

c) a signed patient acknowledgment; and

d) in a patient who has previously been treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Acromegaly

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

**Population criteria:**

- Patient must be aged 18 years or older.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

1) Growth hormone (GH) levels of less than 2.5 mcg/L; and

2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy and the GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of approval.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**pasireotide 60 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

| 10887B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *7847.15 | Signifor LAR [NV] |

**pasireotide 40 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

| 10884W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *7847.15 | Signifor LAR [NV] |

**pasireotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

| 10880P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *7847.15 | Signifor LAR [NV] |

# ANTIINFECTIVES FOR SYSTEMIC USE

## ANTIBACTERIALS FOR SYSTEMIC USE

### MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

*Macrolides*

### ▪ AZITHROMYCIN

**Authority required**

Mycobacterium avium complex infection

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be human immunodeficiency virus (HIV) positive, **AND**
- Patient must have CD4 cell counts of less than 75 per cubic millimetre.

**azithromycin 600 mg tablet, 8**

| 6221K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *122.35 | Zithromax [PF] |

### ▪ CLARITHROMYCIN

**Authority required**

Mycobacterium avium complex infection

**clarithromycin 500 mg tablet, 100**

| 6152T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 2 | .. | 41.61 | APO-Clarithromycin [TX] |

## ▪ ANTIMYCOBACTERIALS

### DRUGS FOR TREATMENT OF TUBERCULOSIS

*Antibiotics*

### ▪ RIFABUTIN

**Authority required**

Mycobacterium avium complex infection

**Clinical criteria:**

- Patient must be human immunodeficiency virus (HIV) positive.

**Authority required**

Mycobacterium avium complex infection

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be human immunodeficiency virus (HIV) positive, **AND**
- Patient must have CD4 cell counts of less than 75 per cubic millimetre.

**rifabutin 150 mg capsule, 30**

| 6195C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 4 | 5 | .. | *646.75 | Mycobutin [PF] |

## ▪ ANTIVIRALS FOR SYSTEMIC USE

### DIRECT ACTING ANTIVIRALS

*Nucleosides and nucleotides excl. reverse transcriptase inhibitors*

### ▪ GANCICLOVIR

**Authority required**

Cytomegalovirus disease

Treatment Phase: Prophylaxis

**Clinical criteria:**

- Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.

**Authority required**

Cytomegalovirus disease

Treatment Phase: Prophylaxis

**Clinical criteria:**

- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

**ganciclovir 500 mg injection, 5 vials**

| 6136Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 1 | .. | *560.43 | Cymevene [RO] |

### ▪ RIBAVIRIN

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**Population criteria:**

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**ribavirin 400 mg tablet, 28**

| 10623D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 2 | .. | 152.75 | Ibavyr [IX] |

**ribavirin 200 mg tablet, 28**

| 10923X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 2 | .. | 81.15 | Ibavyr [IX] |

**ribavirin 600 mg tablet, 28**

| 10675W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 2 | .. | 225.55 | Ibavyr [IX] |

## ▪ RIBAVIRIN

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**Population criteria:**

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**ribavirin 400 mg tablet, 28**

| 10635R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 5 | .. | 152.75 | Ibavyr [IX] |

**ribavirin 200 mg tablet, 28**

| 10938Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 5 | .. | 81.15 | Ibavyr [IX] |

**ribavirin 600 mg tablet, 28**

| 10637W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 5 | .. | 225.55 | Ibavyr [IX] |

## ▪ VALACICLOVIR

**Authority required**

Cytomegalovirus infection and disease

Treatment Phase: Prophylaxis

**Clinical criteria:**

- Patient must have undergone a renal transplant, **AND**
- Patient must be at risk of cytomegalovirus disease.

**valaciclovir 500 mg tablet, 100**

| 6280M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 5 | 2 | .. | *237.00 | [a] APO-Valaciclovir [TX] | [a] Valaciclovir RBX [RA] |
| | | | [B]2.30 | *239.30 | [a] Valtrex [RW] | |

## ▪ VALGANCICLOVIR

**Authority required**

Cytomegalovirus infection and disease

Treatment Phase: Prophylaxis

**Clinical criteria:**

- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

**valganciclovir 50 mg/mL powder for oral liquid, 100 mL**

9675F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 11 | 5 | .. | *#4396.02 | Valcyte [RO] |

**valganciclovir 450 mg tablet, 60**

6357N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *3631.45 | [a] Valcyte [RO]<br>[a] Valganciclovir Juno [JU]<br>[a] Valganciclovir Sandoz [SZ] | [a] Valganciclovir AN [EA]<br>[a] Valganciclovir Mylan [AF] |

*Other antivirals*

## ▪ DACLATASVIR

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**daclatasvir 60 mg tablet, 28**

10631M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 5 | .. | 7713.82 | Daklinza [BQ] |

**daclatasvir 30 mg tablet, 28**

10630L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 5 | .. | 7713.82 | Daklinza [BQ] |

## ▪ DACLATASVIR

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**daclatasvir 60 mg tablet, 28**

10644F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 2 | .. | 7713.82 | Daklinza [BQ] |

**daclatasvir 30 mg tablet, 28**

10643E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 2 | .. | 7713.82 | Daklinza [BQ] |

## ▪ GRAZOPREVIR + ELBASVIR

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**grazoprevir 100 mg + elbasvir 50 mg tablet, 28**

| 10979W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 2 | .. | 21047.15 | Zepatier [MK] |

## ▪ GRAZOPREVIR + ELBASVIR

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**
Chronic hepatitis C infection
**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

**grazoprevir 100 mg + elbasvir 50 mg tablet, 28**

| 10991L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 3 | .. | 21047.15 | Zepatier [MK] |

## ▪ LEDIPASVIR + SOFOSBUVIR

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**
Chronic hepatitis C infection
**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 8 weeks.

**ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28**

| 10653Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 1 | .. | 22113.82 | Harvoni [GI] |

## ▪ LEDIPASVIR + SOFOSBUVIR

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**
Chronic hepatitis C infection
**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28**

| 10672Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 2 | .. | 22113.82 | Harvoni [GI] |

## ▪ LEDIPASVIR + SOFOSBUVIR

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**
Chronic hepatitis C infection
**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28**

| 10679C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 5 | .. | 22113.82 | Harvoni [GI] |

## ▪ PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**
Chronic hepatitis C infection
**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56], 4 x 28**

| 10749R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 2 | .. | 13900.28 | Viekira Pak [VE] |

## ▪ PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR & RIBAVIRIN

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**
Chronic hepatitis C infection
**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**Population criteria:**

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 600 mg tablet [56], 1 pack**

| 10750T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 2 | .. | 13900.28 | Viekira Pak-RBV [VE] |

**paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 200 mg tablet [168], 1 pack**

| 10753Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 2 | .. | 13900.28 | Viekira Pak-RBV [VE] |

## ▪ PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR & RIBAVIRIN

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**
Chronic hepatitis C infection
**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**Population criteria:**

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 600 mg tablet [56], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10773B | 1 | 5 | .. | 13900.28 | Viekira Pak-RBV [VE] |

**paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 200 mg tablet [168], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10761J | 1 | 5 | .. | 13900.28 | Viekira Pak-RBV [VE] |

HSD (Private)

## ▪ SOFOSBUVIR

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**
Chronic hepatitis C infection
**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**sofosbuvir 400 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10654R | 1 | 2 | .. | 19344.90 | Sovaldi [GI] |

## ▪ SOFOSBUVIR

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**
Chronic hepatitis C infection
**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**sofosbuvir 400 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10676X | 1 | 5 | .. | 19344.90 | Sovaldi [GI] |

## ▪ SOFOSBUVIR + VELPATASVIR

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**
Chronic hepatitis C infection
**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**sofosbuvir 400 mg + velpatasvir 100 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 11144M | 1 | 2 | .. | 22113.82 | Epclusa [GI] |

# ▪ ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

## ▪ ANTINEOPLASTIC AGENTS

### ANTIMETABOLITES

*Pyrimidine analogues*

## ▪ AZACITIDINE

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Myelodysplastic syndrome

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR
- The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS).

Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:

a. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR

b. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR

c. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR

d. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR

e. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR

f. Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

a. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR

b. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR

c. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR

d. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

The first authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and

(c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and

(d) a copy of the full blood examination report; and

(e) a copy of the pathology report detailing the cytogenetics demonstrating intermediate-2 or high risk disease according to the International Prognostic Scoring System (IPSS); and

(f) a signed patient acknowledgment form.

No more than 3 cycles will be authorised.

**Authority required**

Chronic Myelomonocytic Leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder.

The first authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and

(c) a copy of the bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia ; and

(d) a copy of the full blood examination report; and

(e) a signed patient acknowledgement.

No more than 3 cycles will be authorised.

**Authority required**

Acute Myeloid Leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

The first authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and

(c) a copy of the bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and
(d) a copy of the full blood examination report; and
(e) a signed patient acknowledgement.
No more than 3 cycles will be authorised.

**azacitidine 100 mg injection, 1 vial**

6100C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 14 | 2 | .. | *5219.35 | [a] Azacitidine Accord [OC]<br>[a] Azadine [RZ]<br>[a] Vidaza [CJ] | [a] AZACITIDINE DR.REDDY'S [RI]<br>[a] Celazadine [JU] |

## ▪ AZACITIDINE

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**
Myelodysplastic syndrome
Treatment Phase: Continuing treatment
**Clinical criteria:**
- The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR
- The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.
Up to 6 cycles will be authorised.

**Authority required**
Chronic Myelomonocytic Leukaemia
Treatment Phase: Continuing treatment
**Clinical criteria:**
- The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.
Up to 6 cycles will be authorised.

**Authority required**
Acute Myeloid Leukaemia
Treatment Phase: Continuing treatment
**Clinical criteria:**
- The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.
Up to 6 cycles will be authorised.

**azacitidine 100 mg injection, 1 vial**

6138C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 14 | 5 | .. | *5219.35 | [a] Azacitidine Accord [OC]<br>[a] Azadine [RZ]<br>[a] Vidaza [CJ] | [a] AZACITIDINE DR.REDDY'S [RI]<br>[a] Celazadine [JU] |

# CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

*Anthracyclines and related substances*

## ▪ DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL

**Authority required**
Kaposi sarcoma
**Clinical criteria:**
- The condition must be AIDS-related, **AND**
- Patient must have a CD4 cell count of less than 200 per cubic millimetre, **AND**
- The condition must include extensive mucocutaneous involvement.

**Authority required**
Kaposi sarcoma
**Clinical criteria:**
- The condition must be AIDS-related, **AND**
- Patient must have a CD4 cell count of less than 200 per cubic millimetre, **AND**
- The condition must include extensive visceral involvement.

**doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial**

| 6249X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | 5 | .. | *1106.35 | [a] Caelyx [JC] | [a] Liposomal Doxorubicin SUN [RA] |

## OTHER ANTINEOPLASTIC AGENTS

*Monoclonal antibodies*

### ▪ RITUXIMAB

**Note** Risk of end-organ damage or mortality includes a minimum of one of the following:Glomerulonephritis with risk of progression
- Risk to sight including scleritis/episcleritis, sudden visual loss, uveitis, retinal changes (vasculitis/thrombosis/exudates/haemorrhage)
- Bronchial/subglottic obstruction
- Pulmonary haemorrhage
- Parenchymal lung disease
- Sensory neural hearing loss
- Recurrent sinonasal disease requiring recurrent surgical interventions
- Meningitis, organic confusion, seizures, stroke, cord lesion, cranial nerve palsy, sensory peripheral neuropathy, motor mononeuritis multiplex

**Note** Patients could be considered contraindicated, refractory, or unable to tolerate cyclophosphamide for one of the following reasons: Cyclophosphamide is contraindicated as per the TGA approved Product Information;
- Cyclophosphamide is not recommended due to the need to preserve gonad function;
- Patient experiences severe toxicity to cyclophosphamide that warrants cessation of treatment;
- Patient has life- or organ-threatening deterioration at any time during treatment with cyclophosphamide, where the deterioration is thought to be due to severe uncontrolled active vasculitis;
- Commencing a further treatment cycle with cyclophosphamide would exceed the maximum cumulative dose of cyclophosphamide of 25g; or
- Patient's condition with this indication is persistent despite at least 3 months therapy with cyclophosphamide.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment.

**Authority required**

Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)

Treatment Phase: Induction of remission

**Clinical criteria:**
- The treatment must be for the induction of remission, **AND**
- Patient must not have previously received this drug for this condition; OR
- Patient must have received this drug for this condition prior to 1 January 2016, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance of remission

The authority application must be made in writing

**Authority required**

Severe active microscopic polyangiitis

Treatment Phase: Induction of remission

**Clinical criteria:**
- The treatment must be for the induction of remission, **AND**
- Patient must not have previously received this drug for this condition; OR
- Patient must have received this drug for this condition prior to 1 January 2016, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance therapy.

The authority application must be made in writing

**Authority required**

Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)

Treatment Phase: Re-induction of remission

**Clinical criteria:**

- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance of remission

The authority application must be made in writing

**Authority required**

Severe active microscopic polyangiitis

Treatment Phase: Re-induction of remission

**Clinical criteria:**

- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance therapy.

The authority application must be made in writing

**rituximab 100 mg/10 mL injection, 2 x 10 mL vials**

10583B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 782.68 | Mabthera [RO] |

**rituximab 500 mg/50 mL injection, 50 mL vial**

10576P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 1911.37 | Mabthera [RO] |

## ▪ IMMUNOSTIMULANTS

### IMMUNOSTIMULANTS

*Colony stimulating factors*

### ▪ FILGRASTIM

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be undergoing induction or consolidation therapy for acute myeloid leukaemia.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must must be receiving chemotherapy with fludarabine and cyclophosphamide for B-cell chronic lymphocytic leukaemia, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**

- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving first-line chemotherapy for Hodgkin disease, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy for myeloma, **AND**
- Patient must have had a prior episode of febrile neutropenia, **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil for inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide) with the intention of achieving a cure or substantial remission in breast cancer.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen).

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy (first-line chemotherapy with escalated BEACOPP) with the intention of achieving a cure or substantial remission in Hodgkin disease.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in an infant or child with central nervous system tumours.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma.

**Authority required**

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

**Authority required**

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

**Authority required**

Assisting bone marrow transplantation

**Clinical criteria:**

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

**Authority required**

Assisting autologous peripheral blood progenitor cell transplantation

**Clinical criteria:**

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

**Authority required**

Severe congenital neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

**Authority required**

Severe chronic neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

**Authority required**

Chronic cyclical neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

**filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes**

2747N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 4 | 11 | .. | *958.07 | Zarzio [SZ] |

**filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes**

5830W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 11 | .. | *387.51 | Nivestim [PF] |

**filgrastim 300 microgram/mL injection, 10 x 1 mL vials**

6126K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 11 | .. | *958.09 | Neupogen [AN] |

**filgrastim 480 microgram/1.6 mL injection, 10 x 1.6 mL vials**

| 6127L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 11 | .. | *1512.93 | Neupogen [AN] |

**filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes**

| 2733W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 4 | 11 | .. | *1512.91 | Zarzio [SZ] |

**filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes**

| 6292E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 11 | .. | *1512.93 | Neupogen [AN] |

**filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes**

| 9695G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 11 | .. | *1512.93 | Nivestim [PF] |

**filgrastim 480 microgram/0.8 mL injection, 10 x 0.8 mL syringes**

| 1113N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 11 | .. | *1512.93 | TevaGrastim [TB] |

**filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes**

| 1082Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 11 | .. | *958.09 | TevaGrastim [TB] |

**filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes**

| 6291D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 11 | .. | *958.09 | Neupogen [AN] |

**filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes**

| 9693E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 11 | .. | *958.09 | Nivestim [PF] |

## ▪ LENOGRASTIM

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving first-line chemotherapy for Hodgkin disease, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in an infant or child with central nervous system tumours.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Ewing's sarcoma.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin's lymphoma (intermediate or high grade).

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in osteosarcoma.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in rhabdomyosarcoma.

**Authority required**

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

**Authority required**

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

**Authority required**

Assisting peripheral blood progenitor cell or bone marrow transplantation

**Clinical criteria:**

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

**LENOGRASTIM Powder for injection 13,400,000 i.u. (105 micrograms) vial, 10**

6337M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 11 | .. | *1019.87 | Granocyte 13 [PF] |

**LENOGRASTIM Powder for injection 33,600,000 i.u. (263 micrograms) vial, 10**

6338N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 11 | .. | *2485.99 | Granocyte 34 [PF] |

## ▪ LIPEGFILGRASTIM

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be undergoing induction or consolidation therapy for acute myeloid leukaemia.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must must be receiving chemotherapy with fludarabine and cyclophosphamide for B-cell chronic lymphocytic leukaemia, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving first-line chemotherapy for Hodgkin disease, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy for myeloma, **AND**
- Patient must have had a prior episode of febrile neutropenia, **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil for inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide) with the intention of achieving a cure or substantial remission in breast cancer.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen).

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy (first-line chemotherapy with escalated BEACOPP) with the intention of achieving a cure or substantial remission in Hodgkin disease.



**lipegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe**

10931H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 11 | .. | 1297.15 | Lonquex [TB] |

## ▪ PEGFILGRASTIM

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be undergoing induction or consolidation therapy for acute myeloid leukaemia.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must must be receiving chemotherapy with fludarabine and cyclophosphamide for B-cell chronic lymphocytic leukaemia, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving first-line chemotherapy for Hodgkin disease, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy for myeloma, **AND**
- Patient must have had a prior episode of febrile neutropenia, **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil for inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR

- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide) with the intention of achieving a cure or substantial remission in breast cancer.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen).

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy (first-line chemotherapy with escalated BEACOPP) with the intention of achieving a cure or substantial remission in Hodgkin disease.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in an infant or child with central nervous system tumours.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma.

**pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe**

6363X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 11 | .. | 1297.15 | [a] Neulasta [AN] | [a] Ristempa [GV] |

*Interferons*

## ▪ INTERFERON ALFA-2A

**Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required**

Chronic Myeloid Leukaemia (CML)

**Clinical criteria:**

- The condition must be Philadelphia chromosome positive.

**interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe**

| 6210W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 30 | 5 | .. | *890.35 | Roferon-A [RO] |

**interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe**

| 6213B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 30 | 5 | .. | *2594.35 | Roferon-A [RO] |

## ▪ INTERFERON ALFA-2B

**Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required**

Chronic Myeloid Leukaemia (CML)

**Clinical criteria:**

- The condition must be Philadelphia chromosome positive.

**Authority required**

Malignant melanoma

**Clinical criteria:**

- The treatment must be as adjunctive therapy to current standard care, **AND**
- Patient must have undergone surgery, **AND**
- The condition must include nodal involvement.

**interferon alfa-2b 30 million units/1.2 mL injection, 1.2 mL**

| 6254E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *595.81 | Intron A Redipen [MK] |

**interferon alfa-2b 60 million units/1.2 mL injection, 1.2 mL**

| 6255F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1179.17 | Intron A Redipen [MK] |

**interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL**

| 6253D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *360.33 | Intron A Redipen [MK] |

**interferon alfa-2b 18 million units/3 mL injection, 3 mL vial**

| 6218G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 15 | 5 | .. | *2594.20 | Intron A [MK] |

**interferon alfa-2b 10 million units/mL injection, 5 x 1 mL vials**

| 6246R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 3 | 5 | .. | *1462.18 | Intron A [MK] |

**interferon alfa-2b 25 million units/2.5 mL injection, 2.5 mL vial**

| 6219H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 15 | 5 | .. | *3584.80 | Intron A [MK] |

## ▪ INTERFERON GAMMA-1B

**Authority required**

Chronic granulomatous disease

**Clinical criteria:**

- Patient must have frequent and severe infections despite adequate prophylaxis with antimicrobial agents.

**interferon gamma-1b 2 million units (100 microgram)/0.5 mL injection, 6 x 0.5 mL vials**

| 6148N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 11 | .. | *2632.87 | Imukin [BY] |

## ▪ PEGINTERFERON ALFA-2A

**Caution** Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Note** Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

**Authority required**

Chronic hepatitis C infection

**Treatment criteria:**

- Must be treated in an accredited treatment centre.

**Population criteria:**

- Patient must be aged 18 years or older, **AND**
- Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age.

**Clinical criteria:**

- Patient must have compensated liver disease, **AND**
- Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, **AND**
- Patient must have a contraindication to ribavirin, **AND**
- The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, **AND**
- The treatment must be limited to a maximum duration of 48 weeks.

Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

**peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

| 6449K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *2612.59 | Pegasys [RO] |

**peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

| 6439X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *2262.37 | Pegasys [RO] |

## ▪ PEGINTERFERON ALFA-2A

**Caution** Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

| 11044G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 2 | .. | 1329.87 | Pegasys [RO] |

*Other immunostimulants*

## ▪ PLERIXAFOR

**Note** Applications for increased maximum quantities will only be authorised for patients with body weight greater than 100 kg.

**Authority required**

Mobilisation of haematopoietic stem cells

**Clinical criteria:**

- The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF), **AND**
- Patient must have lymphoma; OR
- Patient must have multiple myeloma, **AND**
- Patient must require autologous stem cell transplantation, **AND**
- Patient must have failed previous stem cell collection; OR
- Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; OR
- Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

**plerixafor 24 mg/1.2 mL subcutaneous infusion injection, 1.2 mL vial**

| 10084R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 1 | .. | 7038.15 | Mozobil [GZ] |

# IMMUNOSUPPRESSANTS

## IMMUNOSUPPRESSANTS

*Selective immunosuppressants*



### ABATACEPT

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding

rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.



**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
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Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**abatacept 250 mg injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 9621J | 1 | .. | .. | 284.14 | Orencia [BQ] |

## ▪ ALEMTUZUMAB

**Note** Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.
**Note** Special Pricing Arrangements apply.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Treatment criteria:**

- Must be treated by a neurologist.

**alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial**

| 10246G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 3 | .. | .. | *34229.14 | Lemtrada [GZ] |

## ▪ ALEMTUZUMAB

**Note** Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

HSD (Private)

**Authority required**

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial**

| 10243D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 5 | .. | .. | *57017.15 | Lemtrada [GZ] |

## ▪ ECULIZUMAB

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment, according to the specified dosage in the approved Product Information (PI).
Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis).
Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:
a) Active malignancy;
b) Active HIV infection;
c) Hematopoietic stem cell transplants;
d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
f) Active autoimmune diseases;
In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

**Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:
a) Presenting clinical features, including history, acute treatment and medications;
b) Results of testing for genetic mutations (if available);
c) Family history of aHUS, especially in first-degree relatives;
d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;
e) Exclusion of alternative causes of TMA;
f) History of renal or other organ transplant (if any);
g) Any other matters considered relevant by the prescriber.
In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

**Note** The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have active and progressing thrombotic microangiopathy (TMA) caused by aHUS, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than 30x10^9/L and a serum creatinine of greater than 150 mol/L, **AND**
- Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days, **AND**
- Patient must have clinical features of active organ damage or impairment, **AND**
- Patient must not receive more than 4 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Evidence of active and progressing TMA is defined by the following:

(1) a platelet count of less than 150x10^9/L; and evidence of two of the following:

(i) presence of schistocytes on blood film;

(ii) low or absent haptoglobin;

(iii) lactate dehydrogenase (LDH) above normal range;

OR

(2) in recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; AND

(3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one of the following:

(i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or

(ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or

(iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or

(iv) a renal biopsy consistent with aHUS;

(b) onset of TMA-related neurological impairment;

(c) onset of TMA-related cardiac impairment;

(d) onset of TMA-related gastrointestinal impairment;

(e) onset of TMA-related pulmonary impairment.

Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised eculizumab (where possible), and should be supported by objective clinical measures. The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form - Initial PBS-subsidised eculizumab treatment; and

(3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and

(4) A detailed cover letter from the prescriber; and

(5) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and

(6) A measurement of body weight at the time of application; and

(7) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay; and

(8) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 1-2 weeks following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to the Department of Human Services within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under **Initial treatment 1-balance of supply**; and

(9) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days; and

(10) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within one month of application; and

(11) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.

**eculizumab 300 mg/30 mL injection, 30 mL vial**

10182X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 5984.65 | Soliris [XI] |

## ▪ ECULIZUMAB

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 4 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:
a) Active malignancy;
b) Active HIV infection;
c) Hematopoietic stem cell transplants;
d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
f) Active autoimmune diseases;
In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

**Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:
a) Presenting clinical features, including history, acute treatment and medications;
b) Results of testing for genetic mutations (if available);
c) Family history of aHUS, especially in first-degree relatives;
d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;
e) Exclusion of alternative causes of TMA;
f) History of renal or other organ transplant (if any);
g) Any other matters considered relevant by the prescriber.
In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

**Note** The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment - Balance of Supply

**Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

**Clinical criteria:**

- Patient must have received PBS-subsidised initial supply of eculizumab for this condition, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample, **AND**
- Patient must not receive more than 20 weeks supply under this restriction.

ADAMTS-13 activity result must have been submitted to the Department of Human Services. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for **Initial Treatment,** ADAMTS-13 activity must have been measured 1-2 weeks following the last plasma exchange or infusion, and must have been submitted to the Department of Human Services within 27 days of commencement of eculizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the two weeks prior to collection of the ADAMTS-13 assay must also have been provided to Department of Human Services.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

**eculizumab 300 mg/30 mL injection, 30 mL vial**

10192K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 4 | .. | 5984.65 | Soliris [XI] |

## ▪ ECULIZUMAB

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 6 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note** For patients who have received continuing treatment with PBS-subsidised eculizumab prior to 1 January 2016, this restriction is limited to 28 weeks of therapy.

**Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:
a) Active malignancy;
b) Active HIV infection;
c) Hematopoietic stem cell transplants;
d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
f) Active autoimmune diseases;
In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.



**Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:
a) Presenting clinical features, including history, acute treatment and medications;
b) Results of testing for genetic mutations (if available);
c) Family history of aHUS, especially in first-degree relatives;
d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;
e) Exclusion of alternative causes of TMA;
f) History of renal or other organ transplant (if any);
g) Any other matters considered relevant by the prescriber.
In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

**Note** The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

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**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended initial treatment - Assessment phase

**Clinical criteria:**

- Patient must have received treatment under the initial restriction with PBS subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must not receive more than 56 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure.

A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

A maximum of up to 56 weeks of treatment is allowed under this restriction, however an application must be submitted at 6 months, 12 months, 18 months and 24 months following commencing PBS-subsidised eculizumab.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Extended Initial treatment; and

(3) A detailed cover letter from the prescriber; and

(4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and

(5) A measurement of body weight at the time of application; and

(6) An identified genetic mutation, if applicable; and

(7) A family history of aHUS, if applicable; and

(8) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and

(9) A history of kidney transplant, if applicable, (especially if required due to aHUS); and

(10) An inclusion of the individual consequences of recurrent disease, if applicable; and

(11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and

(12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.



**eculizumab 300 mg/30 mL injection, 30 mL vial**

10521R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 6 | .. | 5984.65 | Soliris [XI] |

## ▪ ECULIZUMAB

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:
a) Active malignancy;
b) Active HIV infection;
c) Hematopoietic stem cell transplants;
d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
f) Active autoimmune diseases;
In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

**Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:
a) Presenting clinical features, including history, acute treatment and medications;
b) Results of testing for genetic mutations (if available);
c) Family history of aHUS, especially in first-degree relatives;
d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;
e) Exclusion of alternative causes of TMA;
f) History of renal or other organ transplant (if any);
g) Any other matters considered relevant by the prescriber.
In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

**Note** The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received treatment under Extended Initial restriction with PBS subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, **AND**

- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure.

A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and

(3) A detailed cover letter from the prescriber; and

(4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and

(5) A measurement of body weight at the time of application; and

(6) An identified genetic mutation, if applicable; and

(7) A family history of aHUS, if applicable; and

(8) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and

(9) A history of kidney transplant if applicable (especially if required due to aHUS); and

(10) An inclusion of the individual consequences of recurrent disease, if applicable; and

(11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and

(12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended Continuing treatment

**Clinical criteria:**

- Patient must have received treatment under the Continuing treatment with PBS-subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40% on current objective measurement; OR
- Patient must have severe TMA-related neurological impairment; OR
- Patient must have severe TMA-related gastrointestinal impairment; OR
- Patient must have severe TMA-related pulmonary impairment on current objective measurement; OR
- Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 mL/min); OR
- Patient must have a high risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and

(3) A detailed cover letter from the prescriber; and

(4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and

(5) A measurement of body weight at the time of application; and

(6) An identified genetic mutation, if applicable; and

(7) A family history of aHUS, if applicable; and

(8) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and

(9) A history of kidney transplant, if applicable (especially if required due to aHUS); and

(10) An inclusion of the individual consequences of recurrent disease; and

(11) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment; and

(12) Evidence that the patient has had a treatment response including haematological results of no more than 1 month old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 month old at the time of application; and

(13) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(14) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

**Note** All applications should be accompanied by a detailed letter that outlines the objective evidence of high risk of critical organ damage if aHUS recurs. The following evidence may be submitted to establish the patient's level of risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab:

a) Evidence of a mutation known to confer a high risk of aHUS recurrence;

b) Past history of recurrent episodes of active and progressive TMA due to aHUS, prior to the episode that led to current use of eculizumab;

c) Past family history of aHUS recurrence, especially in first-degree relatives;

d) Past history of recurrent aHUS following renal transplant for end-stage renal failure due to aHUS.

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**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have demonstrated treatment response to previous treatment with PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must have the following clinical conditions:(i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal;AND(ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count <150 x 10^9/L);OR(iii) TMA-related organ impairment including on recent biopsy, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form(s); and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Recommencement of treatment; and

(3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and

(4) A detailed cover letter from the prescriber; and

(5) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and

(6) A measurement of body weight at the time of application, and

(7) An identified genetic mutation, if applicable; and

(8) A family history of aHUS if applicable; and

(9) A history of multiple episodes of aHUS following the treatment break, if applicable; and

(10) A history of kidney transplant if applicable (especially if required due to aHUS); and

(11) An inclusion of the individual consequences of recurrent disease; and

(12) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;

(13) Evidence that the patient has had a treatment response to their previous treatment with eculizumab; and

(14) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(15) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

**Note** A raise in LDH alone is not a sufficient reason to re-commence eculizumab, but thrombocytopenia with one marker of haemolysis (such as raised LDH, presence of schistocytes, or low/absence of haptoglobin) is an accepted reason to consider re-commencement of eculizumab treatment.

**Note** Kidney transplantation/dialysis is not a contraindication to recommencement of eculizumab treatment.

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**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing recommencement of treatment

**Clinical criteria:**

- Patient must have received treatment under Recommencement of treatment restriction with PBS-subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated ongoing treatment response to the previous 24 weeks of PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form; and
(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
(3) A detailed cover letter from the prescriber; and
(4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
(5) A measurement of body weight at the time of application; and
(6) An identified genetic mutation, if applicable; and
(7) A family history of aHUS, if applicable; and
(8) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and
(9) A history of kidney transplant if applicable (especially if required due to aHUS); and
(10) An inclusion of the individual consequences of recurrent disease, if applicable; and
(11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and
(12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
(13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.
This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

**eculizumab 300 mg/30 mL injection, 30 mL vial**

| 10194M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 5 | .. | 5984.65 | Soliris [XI] |

## ▪ EVEROLIMUS

**Caution** Careful monitoring of patients is mandatory.

**Authority required**
Management of renal allograft rejection
Treatment Phase: Management (initiation, stabilisation and review of therapy)
**Clinical criteria:**
- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**Authority required**
Management of cardiac allograft rejection
Treatment Phase: Management (initiation, stabilisation and review of therapy)
**Clinical criteria:**
- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**everolimus 750 microgram tablet, 60**

| 6461C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 4 | 5 | .. | *2786.59 | Certican [NV] |

**everolimus 1 mg tablet, 60**

| 9582H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 4 | 5 | .. | *3699.71 | Certican [NV] |

**everolimus 500 microgram tablet, 60**

| 6460B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *956.81 | Certican [NV] |

**everolimus 250 microgram tablet, 60**

| 6459Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *481.99 | Certican [NV] |

## ▪ MYCOPHENOLATE

**Caution** Careful monitoring of patients is mandatory.

**Authority required**
Management of renal allograft rejection
Treatment Phase: Management (initiation, stabilisation and review of therapy)
**Clinical criteria:**
- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**Authority required**

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL**

6364Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 5 | .. | *#518.46 | CellCept [RO] |

**mycophenolate mofetil 500 mg tablet, 50**

6209T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 6 | 5 | .. | *281.47 | [a] APO-Mycophenolate [TX] | [a] CellCept [RO] |
| | | | | [a] Ceptolate [AF] | [a] Mycophenolate AN [EA] |
| | | | | [a] Mycophenolate Sandoz [SZ] | [a] Pharmacor Mycophenolate 500 [CR] |

## ▪ MYCOPHENOLATE

**Caution** Careful monitoring of patients is mandatory.

**Note** Management includes initiation, stabilisation and review of therapy as required.

**Authority required**

Prophylaxis of renal allograft rejection

Treatment Phase: Management

**Clinical criteria:**

- The treatment must be under the supervision and direction of a transplant unit.

**Authority required**

WHO Class III, IV or V lupus nephritis

Treatment Phase: Management

**Clinical criteria:**

- The condition must be proven by biopsy.

**Treatment criteria:**

- Must be treated by a nephrologist or in consultation with a nephrologist.

The name of the consulting nephrologist must be included in the patient medical records.

**mycophenolate 360 mg enteric tablet, 120**

6370G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 5 | .. | *363.99 | Myfortic [NV] |

**mycophenolate 180 mg enteric tablet, 120**

6369F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 5 | .. | *185.59 | Myfortic [NV] |

## ▪ MYCOPHENOLATE

**Caution** Careful monitoring of patients is mandatory.

**Note** For item codes 6208R and 1837Q, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution.

**Authority required**

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**Authority required**

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy )

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**mycophenolate mofetil 250 mg capsule, 100**

6208R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 6 | 5 | .. | *281.59 | [a] APO-Mycophenolate [TX] | [a] CellCept [RO] |
| | | | | [a] Mycophenolate Sandoz [SZ] | [a] Pharmacor Mycophenolate 250 [CR] |

**mycophenolate Capsule 250 mg, 50**

| 1837Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 12 | 5 | .. | *281.59 | [a] Ceptolate [AF] |

## ▪ NATALIZUMAB

**Caution** Progressive multifocal leukoencephalopathy has been reported with this drug.

**Authority required**

Clinically definite relapsing-remitting multiple sclerosis

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support), **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years, **AND**
- The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; OR
- Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient.

**Population criteria:**

- Patient must be aged 18 years or older.

The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.

Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

**Authority required**

Clinically definite relapsing-remitting multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate, this therapy.

Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

**natalizumab 300 mg/15 mL injection, 15 mL vial**

| 9624M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 5 | .. | 1536.79 | Tysabri [BD] |

## ▪ SIROLIMUS

**Caution** Careful monitoring of patients is mandatory.

**Authority required**

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**sirolimus 2 mg tablet, 100**

| 6457W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *2795.83 | Rapamune [PF] |

**sirolimus 1 mg tablet, 100**

| 6436R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1421.47 | Rapamune [PF] |

**sirolimus 1 mg/mL oral liquid, 60 mL**

| 6437T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *931.91 | Rapamune [PF] |

**sirolimus 500 microgram tablet, 100**

| 9748C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *721.81 | Rapamune [PF] |

## ▪ VEDOLIZUMAB

**Note** Special Pricing Arrangements apply.

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of infliximab, vedolizumab and adalimumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either infliximab, vedolizumab or adalimumab at any one time. From 1 December 2016, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial each of PBS-subsidised infliximab, vedolizumab or adalimumab without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with infliximab, vedolizumab or adalimumab while they continue to show a response to therapy. A patient who received PBS-subsidised infliximab, vedolizumab or adalimumab treatment prior to 1 December 2016 is considered to be in their first cycle as of 1 December 2016. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised infliximab, vedolizumab or adalimumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised infliximab, vedolizumab or adalimumab treatment in the most recent cycle to the date of the first application for initial treatment with infliximab, vedolizumab or adalimumab under the new treatment cycle. A patient who has failed fewer than 3 trials of either infliximab, vedolizumab or adalimumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

(1) How to prescribe PBS-subsidised treatment with infliximab, vedolizumab and adalimumab after therapy after 1 December 2016 .

(a) Initial treatment. Applications for initial treatment should be made where:

(i) an adult patient has received no prior PBS-subsidised treatment with infliximab, vedolizumab or adalimumab in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) an adult patient has received prior PBS-subsidised (initial or continuing) infliximab, vedolizumab or adalimumab therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) an adult patient wishes to re-commence treatment with infliximab, vedolizumab or adalimumab following a break in PBS-subsidised therapy with the same agent (Initial 2).

Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab , 14 weeks of therapy for infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab, and this assessment must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is provided to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with infliximab, vedolizumab or adalimumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment. Assessments of response to a course of PBS-subsidised therapy must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate infliximab, vedolizumab or adalimumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy. A patient may trial an alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with infliximab, vedolizumab or adalimumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate infliximab, vedolizumab or adalimumab therapy should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Mayo clinic score or partial Mayo clinic score submitted with the first authority application for infliximab, vedolizumab or adalimumab. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is provided within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised infliximab, vedolizumab or adalimumab therapy of at least 5 years, must requalify for initial treatment with respect to the scores of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment

withdrawal to these agents) immediately prior to the time the Mayo score is measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.
A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 December 2016 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.



**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment (new patient – Initial 1)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 1 month old at the time of application.

Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose for patients administered doses at weeks 0, 2 and 6 (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

Patients must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

**Note** Details of accepted toxicities including severity can be found on the Department of Human Services website at www.humanservices.gov.au.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

**Note** No applications for increased repeats will be authorised.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Change or Re-commencement of treatment after a break in therapy (Initial 2)

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for adalimumab, infliximab or vedolizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with vedolizumab for this condition more than once in the current treatment cycle, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Population criteria:**

- Patient must be aged 18 years or older.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses of treatment may be requested by telephone by contacting the Department of Human Services.

**Note** No applications for increased repeats will be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (Change or Recommencement of treatment after a break in therapy) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses (Initial 1 and Initial 2 restrictions) or 2 repeats (Continuing restriction), **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

**vedolizumab 300 mg injection, 1 vial**

10398G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 3152.34 | Entyvio [TK] |

## ▪ VEDOLIZUMAB

**Note** No applications for increased maximum quantities will be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).
Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.
From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.
A patient who received PBS-subsidised adalimumab, infliximab,or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.
A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab

and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.
From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.
For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
(b) Continuing treatment.
Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.
A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-

commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.
(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.
A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.



**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment (new patient – initial 1)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, **AND**
- Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR
- Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

**Note** This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe Crohn disease

Treatment Phase: Initial PBS-subsidised treatment (Grandfather)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 August 2015.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with this drug; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug to complete 24 weeks of treatment under the Initial PBS-subsidised treatment restriction for patients who had previously received non-PBS subsidised treatment (Grandfathered patient), **AND**
- The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing or Grandfathered patients), **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

**Note** Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Severe Crohn disease

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests and diagnostic imaging studies, must be made within 1 month of the date of application.

If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

**vedolizumab 300 mg injection, 1 vial**

| 10415E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 3152.34 | Entyvio [TK] |

*Tumor necrosis factor alpha (TNF-) inhibitors*

## ▪ ADALIMUMAB

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have severe active juvenile idiopathic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR
- Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the

baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with adalimumab for this condition in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they

may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient adalimumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient adalimumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with adalimumab, **AND**
- Patient must have received adalimumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline

measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient adalimumab therapy under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

9680L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 1327.01 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

9679K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 1327.01 | Humira [VE] |

**adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

9678J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 1327.01 | Humira [VE] |

## ▪ ETANERCEPT

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have severe active juvenile idiopathic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR
- Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of

methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with etanercept for this condition in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
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HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4

weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient etanercept therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient etanercept therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with etanercept, **AND**
- Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**

- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient etanercept therapy under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

| 9615C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 983.97 | Enbrel [PF] |

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

| 9641K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 983.97 | Enbrel [PF] |

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

6367D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 495.57 | Enbrel [PF] |

## ▪ INFLIXIMAB

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Acute severe ulcerative colitis

**Treatment criteria:**

- Must be treated by a gastroenterologist; OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology].

**Clinical criteria:**

- Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application, **AND**
- Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; OR
- Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below, **AND**
- Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital.

**Population criteria:**

- Patient must be 6 years of age or older.

For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where:

(i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L

(ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood.

For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours.

At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient's medical records.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

**infliximab 100 mg injection, 1 vial**

10057H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 534.87 | [a] Inflectra [PF]<br>[a] Renflexis [MK] | [a] Remicade [JC] |

## ▪ INFLIXIMAB

**Note** Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.
Written applications for authority to prescribe infliximab should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.
From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.
A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment

cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

**Authority required**

Initial 1

Initial treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has an externally draining enterocutaneous or rectovaginal fistula; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6 will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

The authority application must be made in writing

**Authority required**

Initial 2

Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and

(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

The authority application must be made in writing

**Authority required**

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

(a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with infliximab prior to 1 March 2010; and

(b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with infliximab; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) is receiving treatment with infliximab at the time of application; and

(e) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with infliximab.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

The authority application must be made in writing

**Authority required**

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

The authority application must be made in writing

**infliximab 100 mg injection, 1 vial**

9674E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 534.87 | [a] Inflectra [PF]<br>[a] Renflexis [MK] | [a] Remicade [JC] |

## ▪ INFLIXIMAB

**Note** Special Pricing Arrangements apply.

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time.

For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to theDepartment of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient

will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.
For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient with severe disease may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).
A patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PCDAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.
Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.
A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

**Authority required**

Moderate to severe Crohn disease

Treatment Phase: Initial treatment (new paediatric patient) of Crohn disease in a paediatric patient assessed by PCDAI (Initial 1)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have, at the time of application, disease severity considered to be moderate to severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment and which is no more than 1 month old at the time of application.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription forms; and

(b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition; and

(iii) the signed patient or guardian acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Human Services website (www.humanservices.gov.au).

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Moderate to severe Crohn disease

Treatment Phase: Change or re-commencement of treatment of Crohn disease in a paediatric patient assessed by PCDAI (Initial 2)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have a documented history of moderate to severe Crohn disease, **AND**
- Patient must in this treatment cycle, have received prior PBS-subsidised treatment with this drug for this condition; OR

- Patient must in this treatment cycle, have received prior PBS-subsidised treatment with adalimumab for this condition,

**AND**

- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and

(ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Moderate to severe Crohn disease

Treatment Phase: Continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

**Clinical criteria:**

- Patient must have a documented history of moderate to severe Crohn disease.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug as defined as a reduction in PCDAI Score by at least 15 points as compared to baseline and a total of PCDAI score of 30 points or less with the PCDAI assessment being no more than 1 month old at the time of application.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:

(i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with this drug, a PCDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the 'Balance of Supply' treatment phase PBS restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Moderate to severe Crohn disease

Treatment Phase: Balance of supply for a paediatric patient

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under Initial 1 (new patient or patient recommencing treatment after break of more than 5 years) or Initial 2 (change or recommencement of treatment after a break of less than 5 years) or Continuing treatment to complete the maximum duration of treatment specified in the relevant treatment phase, **AND**
- The treatment must provide no more than the balance of up to 3 doses or 2 repeats.

**Note** Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**infliximab 100 mg injection, 1 vial**

9612X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 534.87 | [a] Inflectra [PF]<br>[a] Renflexis [MK] | [a] Remicade [JC] |

## ▪ INFLIXIMAB

**Note** No applications for increased maximum quantities will be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

**Note** **TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological

disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).
Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.
From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.
A patient who received PBS-subsidised adalimumab, infliximab,or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.
A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.
From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.
For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
(b) Continuing treatment.
Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same

treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.
A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.
(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.
A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment (new patient - initial 1)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, **AND**

- Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR
- Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction.

Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing treatment).

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Population criteria:**

- Patient must be aged 18 years or older.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

**Authority required**

Severe Crohn disease

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the

need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

Up to a maximum of 2 repeats will be authorised.

**infliximab 100 mg injection, 1 vial**

| 9613Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 534.87 | [a] Inflectra [PF]<br>[a] Renflexis [MK] | [a] Remicade [JC] |

## ▪ INFLIXIMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of infliximab, vedolizumab and adalimumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either infliximab, vedolizumab or adalimumab at any one time. From 1 December 2016, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial each of PBS-subsidised infliximab, vedolizumab or adalimumab without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with infliximab, vedolizumab or adalimumab while they continue to show a response to therapy. A patient who received PBS-subsidised infliximab, vedolizumab or adalimumab treatment prior to 1 December 2016 is considered to be in their first cycle as of 1 December 2016. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised infliximab, vedolizumab or adalimumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised infliximab, vedolizumab or adalimumab treatment in the most recent cycle to the date of the first application for initial treatment with infliximab, vedolizumab or adalimumab under the new treatment cycle. A patient who has failed fewer than 3 trials of either infliximab, vedolizumab or adalimumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

(1) How to prescribe PBS-subsidised treatment with infliximab, vedolizumab and adalimumab after therapy after 1 December 2016 .

(a) Initial treatment. Applications for initial treatment should be made where:

(i) an adult patient has received no prior PBS-subsidised treatment with infliximab, vedolizumab or adalimumab in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) an adult patient has received prior PBS-subsidised (initial or continuing) infliximab, vedolizumab or adalimumab therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) an adult patient wishes to re-commence treatment with infliximab, vedolizumab or adalimumab following a break in PBS-subsidised therapy with the same agent (Initial 2).

Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab , 14 weeks of therapy for infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab, and this assessment must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is provided to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of an initial treatment course with infliximab, vedolizumab or adalimumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment. Assessments of response to a course of PBS-subsidised therapy must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate infliximab, vedolizumab or adalimumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy. A patient may trial an alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with infliximab, vedolizumab or adalimumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate infliximab, vedolizumab or adalimumab therapy should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Mayo clinic score or partial Mayo clinic score submitted with the first authority application for infliximab, vedolizumab or adalimumab. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is provided within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised infliximab, vedolizumab or adalimumab therapy of at least 5 years, must requalify for initial treatment with respect to the scores of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the Mayo score is measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.
A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 December 2016 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to infliximab and adalimumab only.A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time. Infliximab and adalimumab are PBS-subsidised for moderate to severe disease while only infliximab is PBS-subsidised for acute severe disease.From 1 June 2017, under the PBS, all will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent.Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 June 2017 is considered to be in their first cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 June 2017.(a) Initial treatment.Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient has received prior PBS-subsidised (initial or continuing) treatment with a TNF-alfa antagonist and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping treatment' below]; or (iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following

a break in PBS-subsidised therapy with that agent (Initial 2). Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted tothe Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply. Assessments of response to a course of PBS-subsidised treatment must be submitted the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.(2) Swapping treatment. Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.A patient may trial an alternate agent at any time, regardless of whether they are receiving treatment (initial or continuing) with infliximab or adalimumab at the time of the application. However, a patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PUCAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the PUCAI score is measured.(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab. A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 June 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction.A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

**Note** Special Pricing Arrangements apply.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR

- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years; OR
- Patient must have previously received induction therapy with this drug for an acute severe episode of ulcerative colitis in the last 4 months and demonstrated an adequate response to induction therapy by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 (if aged 6 to 17 years).

**Population criteria:**

- Patient must be 6 years of age or older.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the signed patient acknowledgement or guardian acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 1 month old at the time of application.

Where treatment for an acute severe episode has occurred, an adequate response to induction therapy needs to be demonstrated by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 (if aged 6 to 17 years), within the first 12 weeks of receiving this drug for acute severe ulcerative colitis.

Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 within the first 12 weeks of receiving this drug for ulcerative colitis, or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or have failed to maintain a PUCAI score less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose for patients administered doses at weeks 0, 2 and 6 (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The patient or guardian (required if patient is aged 6 to 17 years) must have signed a patient acknowledgement indicating that he or she understands and acknowledges that the PBS-subsidised treatment will cease if he or she does not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

The authority application must be made in writing

Up to a maximum of 2 repeats will be authorised.

**Note** No applications for increased repeats will be authorised.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Change or Re-commencement of treatment after a break in therapy (Initial 2)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with adalimumab, infliximab or vedolizumab for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with adalimumab or infliximab for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have failed PBS-subsidised treatment with infliximab for this condition in the current treatment cycle; OR
- Patient must not have failed PBS-subsidised treatment with infliximab for this condition in the current treatment cycle more than once if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug.

Applications for authorisation of initial treatment must be in writing and must include:(a) a completed authority prescription form; and(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy];

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Up to a maximum of 2 repeats will be authorised.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

**Note** No applications for increased repeats will be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (Change or Recommencement of treatment after a break in therapy) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses (Initial 1 and Initial 2 restrictions) or 2 repeats (Continuing restriction).

**Population criteria:**

- Patient must be 6 years of age or older.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

**infliximab 100 mg injection, 1 vial**

10184B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 534.87 | [a] Inflectra [PF]<br>[a] Renflexis [MK] | [a] Remicade [JC] |

## ▪ INFLIXIMAB

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must have not failed previous PBS-subsidised treatment with infliximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application including severity.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the

C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

If a patient fails to demonstrate a response to a treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the

dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient infliximab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient infliximab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with infliximab, **AND**
- Patient must have received infliximab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats will be authorised.

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the

application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient infliximab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**

- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**infliximab 100 mg injection, 1 vial**

| 6397Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 534.87 | [a] Inflectra [PF]<br>[a] Renflexis [MK] | [a] Remicade [JC] |



## ▪ INFLIXIMAB

**Authority required**

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or secukinumab in this treatment cycle, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 18 weeks of treatment with this drug will be approved under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5

years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be eligible to receive further bDMARD therapy.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 18 weeks of treatment with this drug will be approved under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Grandfather patients - secukinumab only.
For patients who commenced treatment with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction
(c) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

**Clinical criteria:**

- Patient must have active, or a documented history of active, ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 18 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 18 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 18 weeks treatment available under the above restrictions.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001



**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis.
Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.
Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised bDMARD therapy
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Grandfather patients - secukinumab only.
For patients who commenced treatment with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction
(c) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**

- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001



**infliximab 100 mg injection, 1 vial**

6448J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 534.87 | [a] Inflectra [PF]<br>[a] Renflexis [MK] | [a] Remicade [JC] |

## ▪ INFLIXIMAB

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe active psoriatic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001



**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment

course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.
Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
Grandfather patients - ustekinumab and secukinumab only.
For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001



**infliximab 100 mg injection, 1 vial**

6496X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 534.87 | [a] Inflectra [PF]<br>[a] Renflexis [MK] | [a] Remicade [JC] |

## ▪ INFLIXIMAB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.
Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.
Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.
Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.
Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Application for approval for initial treatment.
Applications for a course of initial treatment should be made in the following situations:
(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or
(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that

agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.
Grandfather patients (ixekizumab only).
Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Application for continuing treatment.
Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.
For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
(4) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.
(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii)

cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**

- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) restriction to complete 22 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment

course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

HSD (Private)

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**infliximab 100 mg injection, 1 vial**

9617E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 534.87 | [a] Inflectra [PF]<br>[a] Renflexis [MK] | [a] Remicade [JC] |

*Interleukin inhibitors*

## ▪ ANAKINRA

**Note** This drug is not PBS-subsidised for conditions other than CAPS.

**Authority required (STREAMLINED)**

***5450***

Moderate to severe cryopyrin associated periodic syndromes (CAPS)

**Treatment criteria:**

- Must be treated by a rheumatologist or in consultation with a rheumatologist; OR
- Must be treated by a clinical immunologist or in consultation with a clinical immunologist.

A diagnosis of CAPS must be documented in the patient's medical records.

**anakinra 100 mg/0.67 mL injection, 28 x 0.67 mL syringes**

10263E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
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## ▪ TOCILIZUMAB

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have severe active juvenile idiopathic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR
- Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, **AND**

- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in

their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**

- Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle,

**AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such

therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply.

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with tocilizumab, **AND**
- Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
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**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than

12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment – balance of supply

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to

Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

| 10068X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 114.00 | Actemra [RO] |

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

| 10079L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 272.00 | Actemra [RO] |

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

| 10060L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 534.16 | Actemra [RO] |

HSD (Private)

## ▪ TOCILIZUMAB

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR
- Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

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(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**

- Patient must have demonstrated an adequate response to treatment with tocilizumab, **AND**
- Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
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Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most

recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment – balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

| 10073E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 114.00 | Actemra [RO] |

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

| 10071C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 272.00 | Actemra [RO] |

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

| 10078K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 534.16 | Actemra [RO] |



## ▪ TOCILIZUMAB

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with tocilizumab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A

separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent

(Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.



**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) completed authority prescription form(s); and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to a treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most

recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with tocilizumab, **AND**
- Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

| 9671B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 114.00 | Actemra [RO] |

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

| 9672C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 272.00 | Actemra [RO] |

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

| 9673D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 534.16 | Actemra [RO] |

## ▪ TOCILIZUMAB

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).
From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show a response to therapy, and
(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to respond to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to receive further PBS-subsidised tocilizumab therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was stopped to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.
A patient who was receiving PBS-subsidised tocilizumab treatment immediately prior to 1 May 2012 is considered to be in their first cycle as of 1 May 2012. A patient who has had a break in tocilizumab treatment of at least 12 months immediately prior to making a new application, on or after 1 May 2012, will commence a new treatment cycle.
A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of less than 12 months may commence a second course of treatment within the same treatment cycle.
A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
(1) How to prescribe PBS-subsidised tocilizumab therapy after 1 May 2012.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised tocilizumab treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain a response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2); or
(iv) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab for that course.
For second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with tocilizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted tocilizumab supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.
(2) Treatment cycle.
Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count) or the prior therapy requirements, except if the patient has had a break in therapy of more than 12 months.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.
Where a patient is deemed to have failed to respond or to sustain a response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. The Department of Human Services will assess response according to these revised baseline measurements. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used by the Department of Human Services to assess response to the second course.
(4) Recommencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

**Clinical criteria:**

- Patient must have been diagnosed with systemic juvenile idiopathic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with tocilizumab for this condition; OR
- Patient must not have received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 2 active joints; and

(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or

(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:

(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(ii) details of prior treatment including dose and duration of treatment;

(iii) pathology reports detailing CRP and platelet count where appropriate; and

(3) an acknowledgement signed by a parent or authorised guardian.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to 2 courses of treatment in a treatment cycle they will not be eligible to receive further PBS-subsidised tocilizumab therapy in that treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

**Note** To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be provided for all subsequent continuing treatment applications.

**Note** Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)

**Clinical criteria:**

- Patient must have a documented history of systemic juvenile idiopathic arthritis, **AND**
- Patient must have received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months, **AND**
- Patient must not have failed to demonstrate an adequate response to PBS-subsidised therapy with tocilizumab for this condition more than once in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to that course of treatment with tocilizumab.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

**Note** Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy under the Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy under the Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of systemic juvenile idiopathic arthritis, **AND**
- Patient must have demonstrated an adequate response to their most recent course of PBS-subsidised treatment with tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the most recent prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

**Note** An assessment of the patient's response to a continuing course of therapy should be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001



**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

| 1419Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 114.00 | Actemra [RO] |

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

| 1423X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 272.00 | Actemra [RO] |

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

| 1464C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 534.16 | Actemra [RO] |

## ▪ USTEKINUMAB

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).
Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.
From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab,or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.
A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.
From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.
For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
(b) Continuing treatment.
Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for

adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.
A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.
(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.
A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

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**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment (new patient - initial 1)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug, **AND**
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, **AND**
- Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR
- Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

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**Authority required**

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

**ustekinumab 130 mg/26 mL injection, 26 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 11164N | 4 | .. | .. | *16976.39 | Stelara [JC] |

*Calcineurin inhibitors*

## ▪ CYCLOSPORIN

**Caution** Careful monitoring of patients is mandatory.

**Authority required**

Management of transplant rejection

**Clinical criteria:**

- The treatment must be used by organ or tissue transplant recipients.

**cyclosporin 50 mg/mL injection, 10 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 6109M | 1 | .. | .. | 65.25 | Sandimmun [NV] |

## ▪ CYCLOSPORIN

**Caution** Careful monitoring of patients is mandatory.

**Authority required**

Management of transplant rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must have had an organ or tissue transplantation, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**Authority required**

Severe atopic dermatitis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Treatment criteria:**

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologists.

**Clinical criteria:**

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies.

**Authority required**

Severe psoriasis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies, **AND**
- The condition must have caused significant interference with quality of life.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Authority required**

Nephrotic syndrome

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must have failed prior treatment with steroids and cytostatic drugs; OR
- Patient must be intolerant to treatment with steroids and cytostatic drugs; OR
- The condition must be considered inappropriate for treatment with steroids and cytostatic drugs, **AND**

- Patient must not have renal impairment.

**Treatment criteria:**

- Must be treated by a nephrologist.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- The condition must have been ineffective to prior treatment with classical slow-acting anti-rheumatic agents (including methotrexate); OR
- The condition must be considered inappropriate for treatment with slow-acting anti-rheumatic agents (including methotrexate).

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist.



**cyclosporin 100 mg/mL oral liquid, 50 mL**

| 6125J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 4 | 5 | .. | *1310.31 | Neoral [NV] |

**cyclosporin 10 mg capsule, 60**

| 6232B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *85.55 | Neoral 10 [NV] |

**cyclosporin 50 mg capsule, 30**

| 6353J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | 5 | .. | *286.03 | [a] Cyclosporin Sandoz [SZ] | [a] Neoral 50 [NV] |

**cyclosporin 25 mg capsule, 30**

| 6352H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | 5 | .. | *141.19 | [a] Cyclosporin Sandoz [SZ] | [a] Neoral 25 [NV] |

**cyclosporin 100 mg capsule, 30**

| 6354K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | 5 | .. | *575.39 | [a] Cyclosporin Sandoz [SZ] | [a] Neoral 100 [NV] |

## ▪ TACROLIMUS

**Caution** Careful monitoring of patients is mandatory.

**Authority required**

Management of rejection in patients following organ or tissue transplantation

**Clinical criteria:**

- The treatment must be under the supervision and direction of a transplant unit, **AND**
- The treatment must include initiation, stabilisation, and review of therapy as required.

**tacrolimus 1 mg modified release capsule, 60**

| 9682N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *280.97 | [a] ADVAGRAF XL [LQ] | [a] Prograf XL [LL] |

**tacrolimus 2 mg capsule, 100**

| 10879N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1047.15 | Tacrolimus Sandoz [SZ] |

**tacrolimus 1 mg capsule, 100**

| 6216E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *463.51 | [a] Pacrolim [AF]<br>[a] Prograf [LL]<br>[a] Tacrolimus Sandoz [SZ] | [a] Pharmacor Tacrolimus 1 [CR]<br>[a] TACROLIMUS APOTEX [TX] |

**tacrolimus 5 mg modified release capsule, 30**

| 9683P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *787.61 | [a] ADVAGRAF XL [LQ] | [a] Prograf XL [LL] |

**tacrolimus 5 mg capsule, 50**

| 6217F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1143.59 | [a] Pacrolim [AF]<br>[a] Prograf [LL]<br>[a] Tacrolimus Sandoz [SZ] | [a] Pharmacor Tacrolimus 5 [CR]<br>[a] TACROLIMUS APOTEX [TX] |

**tacrolimus 500 microgram modified release capsule, 30**

| 9681M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *86.19 | [a] ADVAGRAF XL [LQ] | [a] Prograf XL [LL] |

**tacrolimus 750 microgram capsule, 100**

| 10875J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *397.15 | Tacrolimus Sandoz [SZ] |

**tacrolimus 500 microgram capsule, 100**

| 6328C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *235.33 | [a] Pacrolim [AF]<br>[a] Prograf [LL]<br>[a] Tacrolimus Sandoz [SZ] | [a] Pharmacor Tacrolimus 0.5 [CR]<br>[a] TACROLIMUS APOTEX [TX] |

*Other immunosuppressants*

HSD (Private)

## ▪ LENALIDOMIDE

**Note** Special Pricing Arrangements apply.

**Authority required**

Myelodysplastic syndrome

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be limited to a maximum duration of 16 weeks, **AND**
- Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), **AND**
- Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, **AND**
- Patient must be red blood cell transfusion dependent.

Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination: less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias.

Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations:

1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR
2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR
5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias.

Classification of a patient as red blood cell transfusion dependent requires that:

(i) the patient has been transfused within the last 8 weeks; and

(ii) the patient has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and would be expected to continue this requirement without lenalidomide treatment.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Myelodysplastic Syndrome Lenalidomide Authority Application - Supporting Information Form; and

(c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and

(d) a copy of the full blood examination report; and

(e) a copy of the pathology report detailing the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note: using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS -5q is acceptable); and

(f) details of transfusion requirements including: (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red cell units transfused in the 4 and 6 months preceding the date of this application; and

(g) a signed patient acknowledgement form.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), **AND**
- Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, **AND**
- Patient must have received PBS-subsidised initial therapy with lenalidomide for myelodysplastic syndrome, **AND**
- Patient must have achieved and maintained transfusion independence; or least a 50% reduction in red blood cell unit transfusion requirements compared with the four month period prior to commencing initial PBS-subsidised therapy with lenalidomide, **AND**
- Patient must not have progressive disease.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

The first authority application for continuing supply must be made in writing. Subsequent authority applications for continuing supply may be made by telephone.

The following evidence of response must be provided at each application:

(i) a haemoglobin level taken within the last 4 weeks; and

(ii) the date of the last transfusion; and

(iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application; and

(iv) a statement confirming that the patient has not progressed to acute myeloid leukaemia.

**Note** Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Subsequent authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**lenalidomide 5 mg capsule, 21**

2798G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 3 | .. | 5169.91 | Revlimid [CJ] |

**lenalidomide 10 mg capsule, 21**

2796E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 3 | .. | 5408.31 | Revlimid [CJ] |

## ▪ LENALIDOMIDE

**Note** Special Pricing Arrangements apply.

**Authority required**

Multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

**Clinical criteria:**

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Thalidomide treatment failure is defined as:

(1) confirmed disease progression during thalidomide treatment or within 6 months of discontinuing thalidomide treatment; or

(2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment.

Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living.

Toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity.

Failure to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease is defined as:

(1) less than a 25% reduction in serum or urine M protein; or

(2) in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum free light chain levels.

If the dosing requirement for thalidomide cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and

(3) duration of thalidomide and daily dose prescribed; and

(4) a signed patient acknowledgment.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

**Clinical criteria:**

- Patient must have previously received an authority prescription for lenalidomide, **AND**
- Patient must not have progressive disease, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with dexamethasone.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**lenalidomide 15 mg capsule, 21**

| 9644N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 6299.68 | Revlimid [CJ] |

**lenalidomide 5 mg capsule, 21**

| 9642L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 5169.91 | Revlimid [CJ] |

**lenalidomide 25 mg capsule, 21**

| 9645P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 6634.64 | Revlimid [CJ] |

**lenalidomide 10 mg capsule, 21**

| 9643M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 5408.31 | Revlimid [CJ] |



## ▪ LENALIDOMIDE

**Caution** This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

**Note** Special Pricing Arrangements apply.

**Authority required**

Multiple myeloma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be ineligible for a primary stem cell transplantation, **AND**
- Patient must not be receiving PBS subsidised bortezomib for this condition, **AND**
- The treatment must be in combination with dexamethasone.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, and ineligibility for prior stem cell transplant; and nomination of which disease activity parameters will be used to assess response; and

(3) a signed patient acknowledgement.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Patient must be registered in the i-access risk management program.

**Authority required**

Multiple myeloma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been authorised with a PBS prescription with this drug for the condition, **AND**
- Patient must not have demonstrated progressive disease, **AND**
- Patient must not be receiving PBS subsidised bortezomib for this condition, **AND**
- The treatment must be in combination with dexamethasone.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**lenalidomide 15 mg capsule, 21**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 11042E | 1 | .. | .. | 6299.68 | Revlimid [CJ] |

**lenalidomide 5 mg capsule, 21**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 11036W | 1 | .. | .. | 5169.91 | Revlimid [CJ] |

**lenalidomide 25 mg capsule, 21**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 11055W | 1 | .. | .. | 6634.64 | Revlimid [CJ] |

**lenalidomide 10 mg capsule, 21**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 11063G | 1 | .. | .. | 5408.31 | Revlimid [CJ] |

## ▪ POMALIDOMIDE

**Caution** This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

**Note** Special Pricing Arrangements apply.

**Authority required**

Multiple myeloma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in combination with dexamethasone, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must have experienced treatment failure with lenalidomide, **AND**
- Patient must have experienced treatment failure with bortezomib, **AND**
- Patient must not be receiving concomitant PBS-subsidised thalidomide, lenalidomide or bortezomib.

Bortezomib treatment failure is the absence of achieving at least a partial response or as progressive disease during treatment or within 6 months of discontinuing treatment with bortezomib. Lenalidomide treatment failure is progressive disease during treatment or within 6 months of discontinuing treatment with lenalidomide.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma pomalidomide Authority Application Supporting Information form; and

(3) reports demonstrating the patient has failed treatment with lenalidomide and bortezomib.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Multiple myeloma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have progressive disease, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must not be receiving concomitant PBS-subsidised thalidomide, lenalidomide or bortezomib.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**pomalidomide 4 mg capsule, 21**

| 10386P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 10547.15 | Pomalyst [CJ] |

**pomalidomide 3 mg capsule, 21**

| 10417G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 10547.15 | Pomalyst [CJ] |

## ▪ RITUXIMAB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services

no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with rituximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20

mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 2 infusions of rituximab under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'TNF' alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made at least 12 weeks after the first infusion so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services within 4 weeks of the date it was conducted. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient who fails to demonstrate a response to treatment with rituximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who fails to demonstrate a response to rituximab treatment and who qualifies to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 2 infusions of rituximab under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'TNF' alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) completed authority prescription form(s); and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with rituximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised rituximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised rituximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response at least 12 weeks after the first infusion. This assessment must be submitted no later than 4 weeks from the date of the assessment.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient fails to demonstrate a response to a treatment with rituximab and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as the most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition, **AND**
- Patient must not receive more than 2 infusions of rituximab under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) completed authority prescription form(s); and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**rituximab 500 mg/50 mL injection, 50 mL vial**

| 9611W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 1911.37 | Mabthera [RO] |

## ▪ THALIDOMIDE

**Caution** Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

**Note** Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program.

**Authority required**

Multiple myeloma

**thalidomide 100 mg capsule, 28**

| 9684Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | .. | .. | *1643.15 | Thalomid [CJ] |

**thalidomide 50 mg capsule, 28**

| 6469L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 4 | .. | .. | *1643.15 | Thalomid [CJ] |

# ▪ MUSCULO-SKELETAL SYSTEM

# ▪ MUSCLE RELAXANTS

## MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

*Other centrally acting agents*

## ▪ BACLOFEN

**Note** Pharmaceutical benefits that have the form baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule and pharmaceutical benefits that have the form baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules are equivalent for the purposes of substitution.

**Authority required**

Severe chronic spasticity

**Clinical criteria:**

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity of cerebral origin.

**Authority required**

Severe chronic spasticity

**Clinical criteria:**

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to multiple sclerosis.

**Authority required**

Severe chronic spasticity

**Clinical criteria:**

- Patient must have failed to respond to treatment with oral antispastic agents; OR

- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord injury.

**Authority required**

Severe chronic spasticity

**Clinical criteria:**

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord disease.

**baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 6284R | 10 | .. | .. | *1293.45 | [a] Bacthecal [DZ] | [a] Lioresal Intrathecal [NV] |

**baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 11128Q | 1 | .. | .. | 1293.45 | [a] Sintetica Baclofen Intrathecal [BZ] |

HSD (Private)

# DRUGS FOR TREATMENT OF BONE DISEASES

## DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

*Bisphosphonates*

### IBANDRONATE

**Authority required**

Bone metastases

**Clinical criteria:**

- The condition must be due to breast cancer.

**ibandronate 6 mg/6 mL injection, 6 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 9619G | 1 | 11 | .. | 344.41 | Bondronat [RO] |

### PAMIDRONATE DISODIUM

**Authority required**

Hypercalcaemia of malignancy

**Clinical criteria:**

- Patient must have a malignancy refractory to anti-neoplastic therapy.

**pamidronate disodium 60 mg/10 mL injection, 10 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 6288Y | 1 | 2 | .. | 66.41 | Pamisol [PF] |

**pamidronate disodium 15 mg/5 mL injection, 5 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 6286W | 4 | 2 | .. | *66.39 | Pamisol [PF] |

**pamidronate disodium 30 mg/10 mL injection, 10 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 6287X | 2 | 2 | .. | *66.41 | Pamisol [PF] |

### PAMIDRONATE DISODIUM

**Authority required**

Hypercalcaemia of malignancy

**Clinical criteria:**

- Patient must have a malignancy refractory to anti-neoplastic therapy.

**Authority required**

Multiple myeloma

**Authority required**

Bone metastases

**Clinical criteria:**

- The condition must be due to breast cancer.

**pamidronate disodium 90 mg/10 mL injection, 10 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 6289B | 1 | 11 | .. | 94.04 | Pamisol [PF] |

## ▪ ZOLEDRONIC ACID

**Note** Pharmaceutical benefits that have the form zoledronic acid 4 mg/100 mL injection and pharmaceutical benefits that have the form zoledronic acid 4 mg/5 mL injection are equivalent for the purposes of substitution.

**Authority required**

Multiple myeloma

**Authority required**

Bone metastases

**Clinical criteria:**

- The condition must be due to breast cancer.

**Authority required**

Bone metastases

**Clinical criteria:**

- The condition must be due to castration-resistant prostate cancer.

**Authority required**

Hypercalcaemia of malignancy

**Clinical criteria:**

- Patient must have a malignancy refractory to anti-neoplastic therapy.

**zoledronic acid 4 mg/100 mL injection, 100 mL bag**

| 10542W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 11 | .. | 262.29 | [a] DBL Zoledronic Acid [PF] |

**zoledronic acid 4 mg/5 mL injection, 5 mL vial**

| 6371H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 11 | .. | 262.29 | [a] APO-Zoledronic Acid [TX]<br>[a] Zometa [NV] | [a] DBL Zoledronic Acid [PF] |

**zoledronic acid 4 mg/100 mL injection, 100 mL vial**

| 10554L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 11 | .. | 262.29 | [a] Zometa [NV] |

# ▪ NERVOUS SYSTEM

## ▪ ANTI-PARKINSON DRUGS

### DOPAMINERGIC AGENTS

*Dopa and dopa derivatives*

## ▪ LEVODOPA + CARBIDOPA ANHYDROUS

**Note** Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

**Authority required**

Advanced Parkinson disease

**Clinical criteria:**

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- The treatment must be commenced in a hospital-based movement disorder clinic.

**levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL**

| 9744W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 8 | 5 | .. | *11583.15 | Duodopa [VE] |

*Dopamine agonists*

## ▪ APOMORPHINE

**Authority required**

Parkinson disease

**Clinical criteria:**

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.

**apomorphine hydrochloride 100 mg/20 mL injection, 5 x 20 mL vials**

| 11083H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 18 | 5 | .. | *7599.91 | Apomine Solution for Infusion [PF] |

**apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules**

| 9607P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 72 | 5 | .. | *6576.43 | Movapo [TD] |

**apomorphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules**

| 10235Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 72 | 5 | .. | *3068.59 | Apomine [PF] |

**apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules**

| 9640J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 36 | 5 | .. | *8215.15 | Movapo [TD] |

**apomorphine hydrochloride 50 mg/10 mL injection, 5 x 10 mL syringes**

| 10971K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 36 | 5 | .. | *8215.15 | Movapo PFS [TD] |

HSD (Private)

# ▪ PSYCHOLEPTICS

## ANTIPSYCHOTICS

*Diazepines, oxazepines, thiazepines and oxepines*

### ▪ CLOZAPINE

**Note** Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Novartis Clozaril Patient Monitoring System (eCPMS) or Hospira Clopineconnect.

**Authority required**

Schizophrenia

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient.

**Clinical criteria:**

- Patient must be non-responsive to other neuroleptic agents; OR
- Patient must be intolerant of other neuroleptic agents.

Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.

The name of the consulting psychiatrist should be included in the patient's medical records.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

**clozapine 200 mg tablet, 100**

| 6418T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | .. | .. | *511.31 | Clopine 200 [PF] |

**clozapine 25 mg tablet, 100**

| 6101D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *75.79 | [a] Clopine 25 [PF] | [a] Clozaril 25 [NV] |

**clozapine 50 mg tablet, 100**

| 6417R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | .. | .. | *141.61 | Clopine 50 [PF] |

**clozapine 100 mg tablet, 100**

| 6102E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *259.23 | [a] Clopine 100 [PF] | [a] Clozaril 100 [NV] |

**clozapine 50 mg/mL oral liquid, 100 mL**

| 9632Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 147.55 | Clopine Suspension [PF] |

# ▪ RESPIRATORY SYSTEM

# ▪ DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

## OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

*Other systemic drugs for obstructive airway diseases*

### ▪ MEPOLIZUMAB

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 26 to 30 week assessment, to ensure continuity of treatment for those patients who meet the continuation criteria for PBS-subsidised mepolizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

HSD (Private)

**Note** **TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE EOSINOPHILIC ASTHMA**
Patients are eligible to commence a 'mepolizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.
Once a patient has either failed to achieve or maintain a response to mepolizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised mepolizumab therapy before they are eligible to commence the next mepolizumab treatment cycle, or if eligible, an 'omalizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised mepolizumab is stopped to the date of the first application for initial treatment with mepolizumab under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised mepolizumab therapy:
(a) Initial treatment:
Applications for initial treatment should be made where:
i) A patient has received no prior PBS-subsidised mepolizumab treatment and wishes to commence such therapy; or
ii) A patient wishes to recommence treatment with mepolizumab following a break in PBS-subsidised therapy of more than 6 months; or
iii) A patient has received prior PBS-subsidised omalizumab and wishes to commence treatment with mepolizumab after a treatment break of 6 months.
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 32 weeks of therapy for mepolizumab.
(b) Grandfather patients:
For patients who commenced treatment with mepolizumab for uncontrolled severe eosinophilic asthma prior to 1 January 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with mepolizumab will be authorised under this criterion. Approval will be based on the criteria included in the relevant restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with mepolizumab will be assessed under the continuing treatment restriction.
'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.
(c) Continuing treatment:
Following the completion of the initial treatment course with mepolizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with mepolizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing mepolizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.
(2) Baseline measurements to determine response:
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for mepolizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:
A patient who wishes to trial a second or subsequent mepolizumab treatment cycle, or an initial omalizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Uncontrolled severe eosinophilic asthma

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**

- Patient must be under the care of the same physician for at least 12 months, **AND**
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 1 or more occasions in the previous 12 months, **AND**
- Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 6 weeks, **AND**
- Patient must have signed a patient or parent/guardian acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised omalizumab.

**Population criteria:**

- Patient must be aged 12 years or older.

Optimised asthma therapy includes:

(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; AND

(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient must be made at time of application for treatment (to establish baseline score) and again around 26 to 30 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment at around 26 to 30 weeks, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with mepolizumab.

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with mepolizumab or omalizumab within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request 7 repeats to provide for an initial course of mepolizumab sufficient for 32 weeks of therapy.

Mepolizumab and omalizumab may not be used concurrently or within 6 months of each other. A patient is required to have ceased treatment with omalizumab for 6 months prior to initiating treatment with mepolizumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Eosinophilic Asthma Initial PBS Authority Application - Supporting Information Form,

which includes the following:

(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and

(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(iii) the signed patient or parent/guardian acknowledgement; and

(c) a copy of the eosinophil pathology report; and

(d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

**mepolizumab 100 mg injection, 1 vial**

11003D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 7 | .. | 1685.15 | Nucala [GK] |

## ▪ MEPOLIZUMAB

**Note** For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

**Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE EOSINOPHILIC ASTHMA**
Patients are eligible to commence a 'mepolizumab treatment cycle' (initial treatment course with or without continuing

treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.
Once a patient has either failed to achieve or maintain a response to mepolizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised mepolizumab therapy before they are eligible to commence the next mepolizumab treatment cycle, or if eligible, an 'omalizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised mepolizumab is stopped to the date of the first application for initial treatment with mepolizumab under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised mepolizumab therapy:
(a) Initial treatment:
Applications for initial treatment should be made where:
i) A patient has received no prior PBS-subsidised mepolizumab treatment and wishes to commence such therapy; or
ii) A patient wishes to recommence treatment with mepolizumab following a break in PBS-subsidised therapy of more than 6 months; or
iii) A patient has received prior PBS-subsidised omalizumab and wishes to commence treatment with mepolizumab after a treatment break of 6 months.
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 32 weeks of therapy for mepolizumab.
(b) Grandfather patients:
For patients who commenced treatment with mepolizumab for uncontrolled severe eosinophilic asthma prior to 1 January 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with mepolizumab will be authorised under this criterion. Approval will be based on the criteria included in the relevant restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with mepolizumab will be assessed under the continuing treatment restriction.
'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.
(c) Continuing treatment:
Following the completion of the initial treatment course with mepolizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with mepolizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing mepolizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.
(2) Baseline measurements to determine response:
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for mepolizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:
A patient who wishes to trial a second or subsequent mepolizumab treatment cycle, or an initial omalizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Uncontrolled severe eosinophilic asthma

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**

- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised omalizumab.

**Population criteria:**

- Patient must be aged 12 years or older.

An adequate response to mepolizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline,

OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

All applications for continuing treatment with mepolizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 26 to 30weeks after the first dose of PBS-subsidised mepolizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with mepolizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within

4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with mepolizumab.

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with mepolizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of mepolizumab sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Eosinophilic Asthma Continuing PBS Authority Application - Supporting Information Form which includes details of maintenance oral corticosteroid dose; and

(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms

**Note** If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

**Note** It is recommended that second and subsequent applications for continuing treatment are submitted at the time of an 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criteria for PBS-subsidised mepolizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Uncontrolled severe eosinophilic asthma

Treatment Phase: Initial treatment - grandfather patients

**Clinical criteria:**

- Patient must have received non-PBS treatment with this drug for this condition prior to 1 January 2017, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have had, prior to commencement of mepolizumab, a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) Forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or(ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or(iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, **AND**
- Patient must have had blood eosinophil count greater than or equal to 300 cells per microlitre prior to commencement of mepolizumab, **AND**
- Patient must have had a duration of asthma of at least 1 year prior to commencement of mepolizumab, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy prior to mepolizumab therapy despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must have signed a patient or parent/guardian acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, **AND**
- Patient must have demonstrated an adequate response to treatment with mepolizumab, **AND**
- The treatment must not be used in combination with omalizumab.

**Population criteria:**

- Patient must be aged 12 years or older.

**Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Optimised asthma therapy includes:

(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; AND

(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

A review of the patient's records should be conducted to extract pre- and post-mepolizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations. Parameters to establish response are: (i) a reduction in Asthma Control Questionnaire (ACQ-5) score of at least 0.5; and/or(ii) maintenance oral corticosteroid dose reduced by at least 25% from baseline.

The assessment of the patient's response to the initial PBS subsidised course of treatment must be made at around 18 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The same parameters used to establish response to non-PBS-subsidised therapy with mepolizumab should be used for the assessment.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with mepolizumab.

Patients will be eligible to receive continuing courses of mepolizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with mepolizumab or omalizumab within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of mepolizumab sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Eosinophilic Asthma Grandfather PBS Authority Application - Supporting Information Form, which includes the following:

(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and

(ii) details of pre- and post-mepolizumab data on symptoms, quality of life, medication doses, severe exacerbation/s and hospitalisations, and

(iii) the signed patient or parent/guardian acknowledgement; and

(c) a copy of the pre-mepolizumab eosinophil pathology report.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS subsidised mepolizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**mepolizumab 100 mg injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 11014Q | 1 | 5 | .. | 1685.15 | Nucala [GK] |

## ▪ OMALIZUMAB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic spontaneous urticaria

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

**Clinical criteria:**

- The condition must be based on both physical examination and patient history (to exclude any factors that may be triggering the urticaria), **AND**
- Patient must have experienced itch and hives that persist on a daily basis for at least 6 weeks despite treatment with H1 antihistamines, **AND**
- Patient must have failed to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy, **AND**
- Patient must not receive more than 12 weeks of treatment under this restriction.

A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following:

1) a H2 receptor antagonist (150 mg twice per day); or

2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or

3) doxepin (up to 25 mg three times a day)

If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.

A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Chronic Spontaneous Urticaria Omalizumab Initial PBS Authority Application - Supporting Information Form which must include:

(i) demonstration of failure to achieve an adequate response to standard therapy; and

(ii) drug names and doses of standard therapies that the patient has failed; and

(iii) a signed patient acknowledgment that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

**omalizumab 150 mg/mL injection, 1 mL syringe**

11175E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 2 | .. | *859.95 | Xolair [NV] |

## ▪ OMALIZUMAB

**Authority required**

Severe chronic spontaneous urticaria

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

**Clinical criteria:**

- Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks per authorised course of treatment under this restriction.

**Note** A proportion of patients respond to 150 mg 4-weekly so where a substantial improvement has been obtained with a 300 mg dose it is reasonable to back-titrate dose after initial treatment.

**Note** Cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Severe chronic spontaneous urticaria

Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 September 2017, **AND**
- Patient must have documented history of itch and hives that persisted on a daily basis for at least 6 weeks despite treatment with H1 antihistamines prior to commencing non-PBS subsidised treatment with this drug for this condition, **AND**
- Patient must have documented history of failure to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy prior to commencing non-PBS subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR

- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following:

1) a H2 receptor antagonist (150 mg twice per day); or

2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or

3) doxepin (up to 25 mg three times a day)

If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.

A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Chronic Spontaneous Urticaria Omalizumab Initial Grandfather PBS Authority Application - Supporting Information Form which must include:

(i) demonstration of failure to achieve an adequate response to standard therapy; and

(ii) drug names and doses of standard therapies that the patient has failed; and

(iii) a signed patient acknowledgment that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**omalizumab 150 mg/mL injection, 1 mL syringe**

11163M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 5 | .. | *859.95 | Xolair [NV] |

## ▪ OMALIZUMAB

**Note** Special Pricing Arrangements apply.

**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a diagnosis of asthma confirmed and documented by a paediatric respiratory physician, clinical immunologist, or allergist; or paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by the following standard clinical features: forced expiratory volume (FEV1) reversibility or airway hyperresponsiveness or peak expiratory flow (PEF) variability, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE, **AND**
- Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to less than 12 years.

**Treatment criteria:**

- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

**Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months.

Optimised asthma therapy includes:

(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative; AND

(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The initial IgE assessment must be no more than 12 months old at the time of application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used), AND

(b) while receiving optimised asthma therapy in the previous 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) or ACQ-IA assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose, and the assessment of exacerbation rate must be made at around 22 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Paediatric Severe Allergic Asthma Initial PBS Authority Application - Supporting Information form,

which includes the following:

(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(iii) acknowledgement signed by a parent or authorised guardian; and

(c) a copy of the IgE pathology report; and

(d) a completed Asthma Control Questionnaire (ACQ-5) or the Asthma Control Questionnaire interviewer administered version (ACQ-IA) calculation sheet including the date of assessment of the patient's symptoms and is endorsed with the prescriber's signature.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 22 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**
Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.
Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised omalizumab therapy.
(a) Initial treatment:
Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.
All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.
(b) Grandfather patients:
Paediatric patients who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 December

2016 and who continue to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with omalizumab will be authorised under this restriction. Approval will be based on the criteria included in the grandfather restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.

(c) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and The Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of severe allergic asthma, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or ACQ-IA score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 or ACQ-IA score from baseline, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate must be made at around 18 to 22 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Paediatric Severe Allergic Asthma Continuing PBS Authority Application - Supporting Information form which includes details of maintenance oral corticosteroid dose; and

(c) a completed Asthma Control Questionnaire (ACQ-5) or the Asthma Control Questionnaire interviewer administered version (ACQ-IA) calculation sheet including the date of assessment of the patient's symptoms and is endorsed with the signature of the prescriber.

**Note** If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

**Note** For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** **TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**
Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.
Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised omalizumab therapy.
(a) Initial treatment:
Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.
All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.
(b) Grandfather patients:
Paediatric patients who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 December 2016 and who continue to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with omalizumab will be authorised under this restriction. Approval will be based on the criteria included in the grandfather restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.
'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.
(c) Continuing treatment:
Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.
(2) Baseline measurements to determine response:
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and The Department of Human Services will assess response according to these revised baseline measurements.
(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.
(4) Monitoring of patients:
Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

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**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Initial and continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction or Grandfather treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the Initial restriction or up to 24 weeks treatment available under the Continuing or Grandfather restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment under the initial restriction or 24 weeks of treatment under the continuing or grandfather restrictions may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

HSD (Private)

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**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - Grandfather patients

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2016, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have had, prior to commencement of omalizumab, a diagnosis of asthma confirmed and documented by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician, defined by the following standard clinical features: forced expiratory volume (FEV1) reversibility or airway hyperresponsiveness or peak expiratory flow (PEF) variability, **AND**
- Patient must have had a duration of asthma of at least 1 year prior to commencement of omalizumab, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy prior to omalizumab therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must have demonstrated an adequate response to treatment.

**Population criteria:**

- Patient must be aged 6 to less than 12 years.

**Treatment criteria:**

- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

**Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months.

Optimised asthma therapy includes:

(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative; AND

(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

A review of the patient's records should be conducted to extract pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations. Examples of parameters to establish response include:

(i) a reduction in Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire Interviewer Administered (ACQ-IA) score of at least 0.5;

(ii) maintenance oral corticosteroid dose reduced by at least 25% from baseline; and/or

(iii) a reduction in the number of hospitalisations or severe exacerbations requiring use of systemic corticosteroids, compared to the 12 months prior to commencement of omalizumab.

The assessment of the patient's response to the initial PBS subsidised course of treatment must be made at around 18 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The same parameters used to establish response to non-PBS-subsidised therapy with omalizumab should be used for the assessment.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

Patients will be eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

Patients may qualify for PBS-subsidised treatment under this restriction once only.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for an initial course of omalizumab of up to 24 weeks, consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Paediatric Grandfather Severe Allergic Asthma PBS Authority Application - Supporting Information Form, which includes the following:

(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(ii) details of pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations; and

(iii) acknowledgement signed by a parent or authorised guardian.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.

(b) Grandfather patients:

Paediatric patients who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 December 2016 and who continue to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with omalizumab will be authorised under this restriction. Approval will be based on the criteria included in the grandfather restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.

(c) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and The Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic

corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.
(4) Monitoring of patients:
Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

HSD (Private)

**omalizumab 150 mg/mL injection, 1 mL syringe**

| 10968G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 433.55 | Xolair [NV] |

**omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe**

| 10956P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 220.35 | Xolair [NV] |

## ▪ OMALIZUMAB

**Note** Special Pricing Arrangements apply.

**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**

- Patient must be under the care of the same physician for at least 12 months, **AND**
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 1 or more occasions in the previous 12 months, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or RAST, **AND**
- Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL, **AND**
- Patient must have signed a patient or parent/guardian acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised mepolizumab.

**Population criteria:**

- Patient must be aged 12 years or older.

Optimised asthma therapy includes:

(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; AND

(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The initial IgE assessment must be no more than 12 months old at the time of application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 22 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab or mepolizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form,

which includes the following:

(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and

(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(iii) the signed patient or parent/guardian acknowledgement; and

(c) the IgE pathology report; and

(d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 22 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**
Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.
Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next omalizumab treatment cycle or, if eligible, a 'mepolizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab or mepolizumab treatment is stopped to the date of the first application for initial treatment with omalizumab or mepolizumab under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised omalizumab therapy:
(a) Initial treatment:
Applications for initial treatment should be made where:
i) A patient has received no prior PBS-subsidised omalizumab treatment and wishes to commence such therapy; or
ii) A patient wishes to recommence treatment with omalizumab following a break in PBS-subsidised therapy of at least 6 months; or
iii) A patient has received prior PBS-subsidised mepolizumab and wishes to commence treatment with omalizumab after a treatment break of at least 6 months.
All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy of omalizumab.
(b) Continuing treatment:
Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.
(2) Baseline measurements to determine response:
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for omalizumab. For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response. However, prescribers may provide new

baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:
A patient who wishes to trial a second or subsequent omalizumab treatment cycle, or an initial mepolizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.
(4) Monitoring of patients:
Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

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**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - balance of supply

**Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of severe allergic asthma, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised mepolizumab.

**Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Population criteria:**

- Patient must be aged 12 years or older.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction).

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, the assessment of oral corticosteroid dose, and the assessment of time adjusted exacerbation rate must be made at around 18 to 22 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Allergic Asthma PBS Authority Application and Supporting Information Form which includes details of maintenance oral corticosteroid dose; and

(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms and is endorsed with the signature of the prescriber; for patients transitioned from the paediatric to the adolescent/adult restrictions an exacerbation calculation sheet may be submitted.

**Note** If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

**Note** For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**
Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.
Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next omalizumab treatment cycle or, if eligible, a 'mepolizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab or mepolizumab treatment is stopped to the date of the first application for initial treatment with omalizumab or mepolizumab under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised omalizumab therapy:
(a) Initial treatment:
Applications for initial treatment should be made where:
i) A patient has received no prior PBS-subsidised omalizumab treatment and wishes to commence such therapy; or
ii) A patient wishes to recommence treatment with omalizumab following a break in PBS-subsidised therapy of at least 6 months; or
iii) A patient has received prior PBS-subsidised mepolizumab and wishes to commence treatment with omalizumab after a treatment break of at least 6 months.
All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy of omalizumab.
(b) Continuing treatment:
Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.
(2) Baseline measurements to determine response:
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for omalizumab. For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:
A patient who wishes to trial a second or subsequent omalizumab treatment cycle, or an initial mepolizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.
(4) Monitoring of patients:
Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**omalizumab 150 mg/mL injection, 1 mL syringe**

10122R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 433.55 | Xolair [NV] |

**omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe**

10110D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 220.35 | Xolair [NV] |

# COUGH AND COLD PREPARATIONS

## EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

*Mucolytics*

### DORNASE ALFA

**Note** This drug is not PBS-subsidised for use in combination with PBS-subsidised mannitol.
**Note** It is highly desirable that all patients be included in the national cystic fibrosis patient database.

**Authority required**

Cystic fibrosis

**Population criteria:**

- Patient must be 5 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

**Authority required**

Cystic fibrosis

**Clinical criteria:**

- Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR
- Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR
- Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR
- Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.

**Population criteria:**

- Patient must be less than 5 years of age.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented. Treatment with this drug should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.

**Authority required**

Cystic fibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have initiated treatment with dornase alfa at an age of less than 5 years, **AND**
- Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

**Population criteria:**

- Patient must be 5 years of age or older.

Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

**dornase alfa 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules**

6120D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 5 | .. | *2289.15 | Pulmozyme [RO] |

HSD (Private)

## ▪ MANNITOL

**Note** This drug is not PBS-subsidised for use in combination with PBS-subsidised dornase alfa.

**Note** It is highly desirable that all patients be included in the national cystic fibrosis patient database.

**Authority required**

Cystic fibrosis

**Clinical criteria:**

- Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result, **AND**
- Patient must be intolerant or inadequately responsive to dornase alfa.

**Population criteria:**

- Patient must be 6 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

**MANNITOL Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers, 1**

2008Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 4 | 5 | .. | *1783.15 | bronchitol [XA] |

# ▪ OTHER RESPIRATORY SYSTEM PRODUCTS

## OTHER RESPIRATORY SYSTEM PRODUCTS

*Other respiratory system products*

## ▪ IVACAFTOR

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Cystic fibrosis

Treatment Phase: Initial treatment - New patients

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be aged 2 years or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and

(3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and

(4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and

(5) the result of a FEV1 measurement performed within a month prior to the date of application, if aged from 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and

(6) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and

(7) a copy of a sweat chloride result; and

(8) height and weight measurements at the time of application; and

(9) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

**Authority required**

Cystic fibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be aged 2 years or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem,

erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and

(3) the result of a FEV1 measurement performed within one month prior to the date of application, if aged 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and

(4) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and

(5) height and weight measurements at the time of application; and

(6) a measurement of number of days of CF-related hospitalisation (including hospital in the home) in the previous 6 months.



**ivacaftor 150 mg tablet, 56**

10175M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 5 | .. | 22547.15 | Kalydeco [VR] |

## ▪ IVACAFTOR

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Cystic fibrosis

Treatment Phase: Initial treatment - New patients

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be aged 2 years or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and

(3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and

(4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and

(5) the result of a FEV1 measurement performed within a month prior to the date of application, if aged from 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and

(6) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and

(7) a copy of a sweat chloride result; and

(8) height and weight measurements at the time of application; and

(9) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001



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**Authority required**

Cystic fibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be aged 2 years or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and

(3) the result of a FEV1 measurement performed within one month prior to the date of application, if aged 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and

(4) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and

(5) height and weight measurements at the time of application; and

(6) a measurement of number of days of CF-related hospitalisation (including hospital in the home) in the previous 6 months.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Cystic fibrosis

Treatment Phase: Initial treatment - Grandfather patients

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must have received treatment with ivacaftor for this condition prior to 1 May 2017, **AND**
- Patient must have received treatment with ivacaftor within the last 6 months at the time of application, **AND**
- Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be 2 to 5 years of age.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The authority application must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Cystic Fibrosis Ivacaftor Application Supporting Information Form; and

(3) an acknowledgement signed by a parent, or authorised guardian if applicable; and

(4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene performed prior to commencing treatment with ivacaftor; and

(5) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and

(6) a copy of sweat chloride result performed prior to commencing treatment with ivacaftor for this condition; and

(7) height and weight measurements at the time of application; and

(8) height and weight measurements performed immediately prior to commencement of ivacaftor; and

(9) a baseline measurement of number of days of CF-related hospitalisation (including hospital-in-the home) in the 12 months prior to commencement of ivacaftor; and

(10) a measurement of the number of days of CF-related hospitalisation (including hospital-in the home) in the 6 months prior to the date of application; and

(11) dates of prior ivacaftor therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**ivacaftor 75 mg granules, 4 x 14 sachets**

11109Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 5 | .. | 22547.15 | Kalydeco [VR] |

**ivacaftor 50 mg granules, 4 x 14 sachets**

11097C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 5 | .. | 22547.15 | Kalydeco [VR] |

# VARIOUS

## ALL OTHER THERAPEUTIC PRODUCTS

### ALL OTHER THERAPEUTIC PRODUCTS

*Iron chelating agents*

#### DEFERASIROX

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic iron overload

**Clinical criteria:**

- Patient must have a disorder of erythropoiesis.

**deferasirox 125 mg dispersible tablet, 28**

| 6499C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 6 | 5 | .. | *1378.57 | Exjade [NV] |

**deferasirox 250 mg dispersible tablet, 28**

| 6500D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 6 | 5 | .. | *2709.91 | Exjade [NV] |

**deferasirox 500 mg dispersible tablet, 28**

| 9600G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 6 | 5 | .. | *5372.71 | Exjade [NV] |

#### DEFERIPRONE

**Authority required**

Iron overload

**Clinical criteria:**

- Patient must have thalassaemia major, **AND**
- Patient must be unable to take desferrioxamine therapy.

**Authority required**

Iron overload

**Clinical criteria:**

- Patient must have thalassaemia major, **AND**
- Patient must be one in whom desferrioxamine therapy has proven ineffective.

**deferiprone 500 mg tablet, 100**

| 6416Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 6 | 5 | .. | *2615.35 | Ferriprox [TX] |

**deferiprone 100 mg/mL oral liquid, 250 mL**

| 9638G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 5 | 5 | .. | *1117.25 | Ferriprox [TX] |

#### DESFERRIOXAMINE

**Authority required**

Disorders of erythropoiesis

**Clinical criteria:**

- The condition must be associated with treatment-related chronic iron overload.

**desferrioxamine mesilate 2 g injection, 1 vial**

| 6270B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 60 | 5 | .. | *1391.95 | Hospira Pty Limited [PF] |

**desferrioxamine mesilate 500 mg injection, 10 vials**

| 6113R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 40 | 5 | .. | *4301.95 | Hospira Pty Limited [PF] |

*Drugs for treatment of hyperkalemia and hyperphosphatemia*

#### LANTHANUM

**Authority required**

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 9635D | 2 | 5 | .. | *524.41 | Fosrenol [ZI] |

**LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 9637F | 2 | 5 | .. | *886.49 | Fosrenol [ZI] |

**LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 9636E | 2 | 5 | .. | *788.23 | Fosrenol [ZI] |

HSD (Private)

## ▪ SEVELAMER

**Authority required**

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**sevelamer hydrochloride 800 mg tablet, 180**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 9620H | 2 | 5 | .. | *619.71 | Renagel [GZ] |

## ▪ SUCROFERRIC OXYHYDROXIDE

**Authority required**

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**iron (as sucroferric oxyhydroxide) 500 mg tablet: chewable, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10230K | 2 | 5 | .. | *790.75 | Velphoro [FN] |

# Highly Specialised Drugs Program (Public Hospital)

HSD (Public)


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# BLOOD AND BLOOD FORMING ORGANS

## ANTIHEMORRHAGICS

### VITAMIN K AND OTHER HEMOSTATICS

*Other systemic hemostatics*

### ELTROMBOPAG

**Note** No applications for increased repeats will be authorised.

**Authority required**

Severe thrombocytopenia

Treatment Phase: Initial treatment 1 - New patient

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have had a splenectomy, **AND**
- Patient must have failed to acheive an adequate response to, or be intolerant to, corticosteroid therapy following the splenectomy, **AND**
- Patient must have failed to acheive an adequate response to, or be intolerant to, immunoglobulin therapy following the splenectomy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**

- Patient must be an adult.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,

(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and

(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

**Note** Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Authority required**

Severe thrombocytopenia

Treatment Phase: Initial treatment 2 - New patient

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must not have had a splenectomy, **AND**
- Patient must have failed to acheive an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks, **AND**
- Patient must have failed to acheive an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- Patient must be unsuitable for splenectomy due to medical reasons, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**

- Patient must be an adult.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

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(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,

(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and

(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

**Note** Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

HSD (Public)

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**Authority required**

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted treatment

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**

- Patient must be an adult.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised treatment with this drug,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the First continuing PBS-subsidised treatment or Re-initiation of interrupted PBS-subsidised treatment must be made in writing and must include:

(1) a completed authority prescription form, and

(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form , and

(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The platelet count must be no more than one month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

**Note** Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe thrombocytopenia

Treatment Phase: Second or subsequent Continuing treatment

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a continuing response to treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**

- Patient must be an adult.

For the purpose of this restriction, a continuing response to treatment with drug is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with this drug

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

The platelet count must be no more than one month old at the time of application.

Authority applications for second and subsequent periods of continuing therapy may be made by telephone

**Note** Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

**Note** Authority applications for second and subsequent continuing treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Authority required**

Severe thrombocytopenia

Treatment Phase: Initial 1, Initial 2, First Continuing treatment or Re-initiation of interrupted treatment, and Second and Subsequent Continuing treatment - balance of supply

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second and subsequent Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**

- Patient must be an adult.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**eltrombopag 25 mg tablet, 28**

5825N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 5 | .. | 1436.40 | Revolade [NV] |

**eltrombopag 50 mg tablet, 28**

5826P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 5 | .. | 2872.80 | Revolade [NV] |

## ▪ ROMIPLOSTIM

**Authority required**

Severe thrombocytopenia

Treatment Phase: Initial treatment 1 - New patient

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have had a splenectomy, **AND**
- Patient must have failed to acheive an adequate response to, or be intolerant to, corticosteroid therapy following the splenectomy, **AND**
- Patient must have failed to acheive an adequate response to, or be intolerant to, immunoglobulin therapy following the splenectomy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**

- Patient must be an adult.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be requested by telephone. The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,

(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and

(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

**Note** Romiplostim is not PBS-subsidised as an alternative to splenectomy.

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe this drug should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe thrombocytopenia

Treatment Phase: Initial treatment 2 - New patient

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must not have had a splenectomy, **AND**
- Patient must have failed to acheive an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks, **AND**
- Patient must have failed to acheive an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- Patient must be unsuitable for splenectomy due to medical reasons, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**

- Patient must be an adult.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be requested by telephone. The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

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(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,

(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and

(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

**Note** Romiplostim is not PBS-subsidised as an alternative to splenectomy.

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe this drug should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

HSD (Public)

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**Authority required**

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted treatment

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**

- Patient must be an adult.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised treatment with this drug,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

Applications for the First continuing PBS-subsidised treatment or Re-initiation of interrupted PBS-subsidised treatment must be made in writing and must include:

(1) a completed authority prescription form, and

(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form , and

(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The platelet count must be no more than one month old at the time of application.

**Note** Romiplostim is not PBS-subsidised as an alternative to splenectomy.

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe this drug should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a continuing response to treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**

- Patient must be an adult.

For the purpose of this restriction, a continuing response to treatment with drug is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with this drug

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

The platelet count must be no more than one month old at the time of application.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

Authority applications for second and subsequent periods of continuing therapy may be made by telephone

**Note** Romiplostim is not PBS-subsidised as an alternative to splenectomy.

**Note** Authority applications for second and subsequent continuing treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note** Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe this drug should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe thrombocytopenia

Treatment Phase: Initial 1, Initial 2, First Continuing treatment or Re-initiation of interrupted treatment, and Second and Subsequent Continuing treatment - balance of supply

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second and subsequent Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**

- Patient must be an adult.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No applications for increased repeats will be authorised.

**romiplostim 500 microgram injection, 1 vial**

9698K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 1857.25 | Nplate [AN] |

**romiplostim 250 microgram injection, 1 vial**

9696H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 928.63 | Nplate [AN] |

## ANTIANEMIC PREPARATIONS

### OTHER ANTIANEMIC PREPARATIONS

*Other antianemic preparations*

## ▪ DARBEPOETIN ALFA

**Authority required (STREAMLINED)**

***6294***

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**darbepoetin alfa 150 microgram/0.3 mL injection, 0.3 mL syringe**

| 5650J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 8 | 5 | .. | *3709.28 | Aranesp SureClick [AN] |

**darbepoetin alfa 100 microgram/0.5 mL injection, 0.5 mL syringe**

| 5649H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 8 | 5 | .. | *2489.44 | Aranesp SureClick [AN] |

**darbepoetin alfa 150 microgram/0.3 mL injection, 4 x 0.3 mL syringes**

| 5643B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *3709.28 | Aranesp [AN] |

**darbepoetin alfa 50 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

| 5641X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1307.94 | Aranesp [AN] |

**darbepoetin alfa 100 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

| 5651K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *2489.48 | Aranesp [AN] |

**darbepoetin alfa 60 microgram/0.3 mL injection, 0.3 mL syringe**

| 5647F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 8 | 5 | .. | *1535.84 | Aranesp SureClick [AN] |

**darbepoetin alfa 40 microgram/0.4 mL injection, 0.4 mL syringe**

| 5646E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 8 | 5 | .. | *1057.92 | Aranesp SureClick [AN] |

**darbepoetin alfa 20 microgram/0.5 mL injection, 0.5 mL syringe**

| 5645D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 8 | 5 | .. | *637.12 | Aranesp SureClick [AN] |

**darbepoetin alfa 20 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

| 5638R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *637.08 | Aranesp [AN] |

**darbepoetin alfa 30 microgram/0.3 mL injection, 4 x 0.3 mL syringes**

| 5639T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *871.58 | Aranesp [AN] |

**darbepoetin alfa 60 microgram/0.3 mL injection, 4 x 0.3 mL syringes**

| 5642Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1535.82 | Aranesp [AN] |

**darbepoetin alfa 40 microgram/0.4 mL injection, 4 x 0.4 mL syringes**

| 5640W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1057.92 | Aranesp [AN] |

**darbepoetin alfa 80 microgram/0.4 mL injection, 0.4 mL syringe**

| 5648G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 8 | 5 | .. | *2021.60 | Aranesp SureClick [AN] |

**darbepoetin alfa 10 microgram/0.4 mL injection, 4 x 0.4 mL syringes**

| 5637Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *338.28 | Aranesp [AN] |

HSD (Public)

**darbepoetin alfa 80 microgram/0.4 mL injection, 4 x 0.4 mL syringes**

| 5644C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *2021.60 | Aranesp [AN] |

## ▪ EPOETIN ALFA

**Authority required (STREAMLINED)**

***6294***

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**epoetin alfa 1000 units/0.5 mL injection, 6 x 0.5 mL syringes**

| 5714R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *265.34 | Eprex 1000 [JC] |

**epoetin alfa 4000 units/0.4 mL injection, 6 x 0.4 mL syringes**

| 5721D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *806.84 | Eprex 4000 [JC] |

**epoetin alfa 3000 units/0.3 mL injection, 6 x 0.3 mL syringes**

| 5720C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *633.56 | Eprex 3000 [JC] |

**epoetin alfa 2000 units/0.5 mL injection, 6 x 0.5 mL syringes**

| 5719B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *490.96 | Eprex 2000 [JC] |

**epoetin alfa 6000 units/0.6 mL injection, 6 x 0.6 mL syringes**

| 5716W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1192.38 | Eprex 6000 [JC] |

**epoetin alfa 8000 units/0.8 mL injection, 6 x 0.8 mL syringes**

| 5717X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1546.52 | Eprex 8000 [JC] |

**epoetin alfa 20 000 units/0.5 mL injection, 6 x 0.5 mL syringes**

| 5713Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *3682.20 | Eprex 20,000 [JC] |

**epoetin alfa 10 000 units/mL injection, 6 x 1 mL syringes**

| 5722E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1871.78 | Eprex 10000 [JC] |

**epoetin alfa 5000 units/0.5 mL injection, 6 x 0.5 mL syringes**

| 5715T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1004.48 | Eprex 5000 [JC] |

**epoetin alfa 40 000 units/mL injection, 1 mL syringe**

| 5718Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1191.30 | Eprex 40,000 [JC] |

## ▪ EPOETIN BETA

**Authority required (STREAMLINED)**

***6294***

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**epoetin beta 10 000 units/0.6 mL injection, 6 x 0.6 mL syringes**

| 5729M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1871.78 | NeoRecormon [RO] |

**epoetin beta 3000 units/0.3 mL injection, 6 x 0.3 mL syringes**

| 5725H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *633.56 | NeoRecormon [RO] |

**epoetin beta 4000 units/0.3 mL injection, 6 x 0.3 mL syringes**

| 5726J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *806.84 | NeoRecormon [RO] |

**epoetin beta 5000 units/0.3 mL injection, 6 x 0.3 mL syringes**

| 5727K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1004.50 | NeoRecormon [RO] |

**epoetin beta 6000 units/0.3 mL injection, 6 x 0.3 mL syringes**

| 5728L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1192.38 | NeoRecormon [RO] |

**epoetin beta 2000 units/0.3 mL injection, 6 x 0.3 mL syringes**

| 5724G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *490.96 | NeoRecormon [RO] |

## ▪ EPOETIN LAMBDA

**Note** Epoetin lambda should only be administered by the intravenous route.

**Authority required (STREAMLINED)**

***6245***

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**epoetin lambda 8000 units/0.8 mL injection, 6 x 0.8 mL syringes**

| 9594Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1465.12 | Novicrit [SZ] |

**epoetin lambda 2000 units/mL injection, 6 x 1 mL syringes**

| 9669X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *465.12 | Novicrit [SZ] |

**epoetin lambda 1000 units/0.5 mL injection, 6 x 0.5 mL syringes**

| 9668W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *251.38 | Novicrit [SZ] |

**epoetin lambda 3000 units/0.3 mL injection, 6 x 0.3 mL syringes**

| 9670Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *600.22 | Novicrit [SZ] |

**epoetin lambda 5000 units/0.5 mL injection, 6 x 0.5 mL syringes**

| 9589Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *951.62 | Novicrit [SZ] |

**epoetin lambda 6000 units/0.6 mL injection, 6 x 0.6 mL syringes**

| 9591T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1129.62 | Novicrit [SZ] |

**epoetin lambda 10 000 units/mL injection, 6 x 1 mL syringes**

| 9596C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1773.28 | Novicrit [SZ] |

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**epoetin lambda 4000 units/0.4 mL injection, 6 x 0.4 mL syringes**

| 9587N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *764.38 | Novicrit [SZ] |

## ▪ METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA

**Authority required (STREAMLINED)**

***6294***

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**methoxy polyethylene glycol-epoetin beta 360 microgram/0.6 mL injection, 1 x 0.6 mL syringe**

| 5800G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *3160.20 | Mircera [RO] |

**methoxy polyethylene glycol-epoetin beta 50 microgram/0.3 mL injection, 1 x 0.3 mL syringe**

| 5795B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *584.54 | Mircera [RO] |

**methoxy polyethylene glycol-epoetin beta 120 microgram/0.3 mL injection, 1 x 0.3 mL syringe**

| 5798E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1274.56 | Mircera [RO] |

**methoxy polyethylene glycol-epoetin beta 30 microgram/0.3 mL injection, 1 x 0.3 mL syringe**

| 5794Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *350.72 | Mircera [RO] |

**methoxy polyethylene glycol-epoetin beta 75 microgram/0.3 mL injection, 1 x 0.3 mL syringe**

| 5796C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *851.22 | Mircera [RO] |

**methoxy polyethylene glycol-epoetin beta 100 microgram/0.3 mL injection, 1 x 0.3 mL syringe**

| 5797D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1100.88 | Mircera [RO] |

**methoxy polyethylene glycol-epoetin beta 200 microgram/0.3 mL injection, 1 x 0.3 mL syringe**

| 5799F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1828.08 | Mircera [RO] |

# ▪ CARDIOVASCULAR SYSTEM

# ▪ ANTIHYPERTENSIVES

## OTHER ANTIHYPERTENSIVES

*Antihypertensives for pulmonary arterial hypertension*

## ▪ AMBRISENTAN

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**

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- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

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Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs

HSD (Public)

Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

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**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

HSD (Public)

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**ambrisentan 10 mg tablet, 30**

5608E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 2732.65 | Volibris [GK] |

**ambrisentan 5 mg tablet, 30**

5607D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 2732.65 | Volibris [GK] |

## ▪ BOSENTAN

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.
The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services

HSD (Public)

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

HSD (Public)

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.
The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.



**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH

agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.
The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

HSD (Public)

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
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Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**bosentan 125 mg tablet, 60**

5619R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 2295.43 | [a] APO-BOSENTAN [GX] | [a] Bosentan APOTEX [TX] |
| | | | | [a] BOSENTAN-DRLA [RZ] | [a] Bosentan GH [GQ] |

[a] Bosentan Mylan [AF]
[a] Bosentan Sandoz [SZ]
[a] Tracleer [AT]
[a] Bosentan RBX [RA]
[a] BOSLEER [RW]

## ▪ BOSENTAN

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

HSD (Public)

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.
The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.
The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

HSD (Public)

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.
The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs

HSD (Public)

Reply Paid 9826
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

HSD (Public)

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Cessation of treatment (all patients)

**Clinical criteria:**

- Patient must have received approval for initial PBS-subsidised treatment with this agent, **AND**
- Patient must have not responded to prior PBS-subsidised therapy with this agent, **AND**
- The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**bosentan 62.5 mg tablet, 60**

5618Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 2295.43 | [a] APO-BOSENTAN [GX] | [a] Bosentan APOTEX [TX] |
| | | | | [a] BOSENTAN-DRLA [RZ] | [a] Bosentan Mylan [AF] |
| | | | | [a] Bosentan RBX [RA] | [a] Bosentan Sandoz [SZ] |
| | | | | [a] BOSLEER [RW] | [a] Tracleer [AT] |

## ▪ EPOPROSTENOL

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

HSD (Public)

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and

(4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

HSD (Public)

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients) or Initial 2 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

HSD (Public)

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**epoprostenol 1.5 mg injection [1 vial] (&) inert substance diluent [2 x 50 mL vials], 1 pack**

| 11065J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 66.55 | Flolan [GK] |

**epoprostenol 1.5 mg injection, 1 vial**

| 10117L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 66.55 | Veletri [AT] |

**epoprostenol 500 microgram injection, 1 vial**

| 10130E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 33.28 | Veletri [AT] |

**epoprostenol 500 microgram injection [1 vial] (&) inert substance diluent [2 x 50 mL vials], 1 pack**

| 11090Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 33.28 | Flolan [GK] |

## ▪ ILOPROST

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with this agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III drug-induced PAH, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III drug-induced PAH and a mean right atrial pressure greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III drug-induced PAH with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class IV drug-induced PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

HSD (Public)

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or drug-induced PAH and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and

(4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

HSD (Public)

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Note** Special Pricing Arrangements apply.

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs

HSD (Public)

Reply Paid 9826
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

HSD (Public)

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

HSD (Public)

**iloprost 20 microgram/2 mL inhalation solution, 30 x 2 mL ampoules**

5751Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 408.88 | Ventavis [BN] |

## ▪ MACITENTAN

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

HSD (Public)

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

HSD (Public)

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

A maximum of 5 repeats will be authorised.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**

HSD (Public)

- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**macitentan 10 mg tablet, 30**

10136L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 2876.47 | Opsumit [AT] |

## ▪ RIOCIGUAT

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 1 month following cessation of therapy, as recommended by the TGA-approved Product Information.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have WHO Functional Class II, III or IV CTEPH, **AND**
- The condition must be inoperable by pulmonary endarterectomy; OR
- The condition must be recurrent or persistent following pulmonary endarterectomy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated in a centre with expertise in the management of CTEPH.

**Population criteria:**

- Patient must be aged 18 years or older.

CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:

- Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn*sec*$cm^{-5}$ measured at least 90 days after start of full anticoagulation; and
- A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.

CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:

- RHC demonstrating a PVR of greater than 300 dyn*sec*$cm^{-5}$ measured at least 180 days following pulmonary endarterectomy.

Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be provided at the time of application.

Applications for authorisation must be in writing and must include:(1) completed authority prescription forms sufficient for dose titration; and(2) a completed CTEPH PBS Initial Authority Application - Supporting Information form which includes results from the 3 tests below, to establish baseline measurements, where available:(i) RHC composite assessment, and(ii) ECHO composite assessment, and(iii) 6 Minute Walk Test (6MWT); and(3) a signed patient acknowledgment form; and(4) confirmation of evidence of inoperable CTEPH including results of a pulmonary vascular resistance (PVR), a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or(5) confirmation of evidence of recurrent or persistent CTEPH including result of PVR and the date that pulmonary endarterectomy was performed; or(6) confirmation of an echocardiogram demonstrating right ventricular dysfunction.

Where it is not possible to perform all 3 tests above on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:(1) RHC plus ECHO composite assessments;(2) RHC composite assessment plus 6MWT;(3) RHC composite assessment only.

In circumstance where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:(1) ECHO composite assessment plus 6MWT;(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Prescriptions for dose titration must provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

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Approvals for subsequent authority prescription will be limited to 1 month of treatment, The quantity approved must be based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 3 repeats.

The assessment of the patient's response to the initial 20-week course of treatment should be made following the preceding 16 weeks of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must demonstrate stable or responding disease, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated in a centre with expertise in the management of CTEPH.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be in writing and must include:(1) a completed authority prescription form; and(2) a completed CTEPH PBS Continuing Authority Application - Supporting Information form which includes results from the three tests below, where available:(i) RHC composite assessment; and(ii) ECHO composite assessment; and(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to this drug is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease.

The assessment of the patient's response to the continuing 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

The maximum quantity per prescription must be based on the dosage recommendations in the TGA-approved Product Information and be limited to provide sufficient supply for 1 month of treatment.

A maximum of 5 repeats will be authorised.

Applications for continuing treatment with this drug should be made two weeks prior to the completion of the 6-month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate disease stability or improvement to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs

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HOBART TAS 7001

**Authority required**

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Grandfathered patients

**Clinical criteria:**

- Patient must have previously received treatment with this drug for this condition prior to 1 January 2017, **AND**
- Patient must have a documented history of WHO Functional Class II, III or IV CTEPH, **AND**
- The condition must be inoperable by pulmonary endarterectomy; OR
- The condition must be recurrent or persistent following pulmonary endarterectomy.

**Treatment criteria:**

- Must be treated in a centre with expertise in the management of CTEPH.

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised agent for this condition.

**Population criteria:**

- Patient must be aged 18 years or older.

CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:

- Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn*sec*$cm^{-5}$ measured at least 90 days after start of full anticoagulation; and
- A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.

CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:

- RHC demonstrating a PVR of greater than 300 dyn*sec*$cm^{-5}$ measured at least 180 days following pulmonary endarterectomy.

Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be provided at the time of application.

Applications for authorisation must be in writing and must include:(1) A completed authority prescription form; and(2) a completed CTEPH PBS Initial Authority Application - Supporting Information form which includes results from the 3 tests below, to establish baseline measurements, where available:(i) RHC composite assessment, and(ii) ECHO composite assessment, and(iii) 6 Minute Walk Test (6MWT); and(3) a signed patient acknowledgment form; and(4) confirmation of evidence of inoperable CTEPH including results of a pulmonary vascular resistance (PVR), a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or(5) confirmation of evidence of recurrent or persistent CTEPH including result of PVR and the date that pulmonary endarterectomy was performed; or(6) confirmation of an echocardiogram demonstrating right ventricular dysfunction.

Where it is not possible to perform all 3 tests above on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:(1) RHC plus ECHO composite assessments;(2) RHC composite assessment plus 6MWT;(2) RHC composite assessment only.

In circumstance where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:(1) ECHO composite assessment plus 6MWT;(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial treatment restriction to complete a maximum of 20 weeks of treatment; OR
- Patient must have received insufficient therapy with this agent under the Continuing treatment restriction to complete a maximum of 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this agent under the Grandfathering restriction to complete a maximum of 24 weeks of treatment, **AND**

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- The treatment must provide no more than the balance of up to 20 or 24 weeks of treatment available under the above respective restriction, **AND**
- The treatment must be the sole PBS-subsidised agent for this condition.

**Treatment criteria:**

- Must be treated in a centre with expertise in the management of CTEPH.

**Population criteria:**

- Patient must be aged 18 years or older.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

**riociguat 2 mg tablet, 84**

| 11013P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 3435.42 | Adempas [BN] |

**riociguat 1 mg tablet, 84**

| 11020B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 3435.42 | Adempas [BN] |

**riociguat 1 mg tablet, 42**

| 10976Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 1717.71 | Adempas [BN] |

**riociguat 500 microgram tablet, 84**

| 10995Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 3435.42 | Adempas [BN] |

**riociguat 1.5 mg tablet, 84**

| 10977R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 3435.42 | Adempas [BN] |

**riociguat 2 mg tablet, 42**

| 10984D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 1717.71 | Adempas [BN] |

**riociguat 2.5 mg tablet, 84**

| 11019Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 3435.42 | Adempas [BN] |

**riociguat 2.5 mg tablet, 42**

| 11002C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 1717.71 | Adempas [BN] |

**riociguat 500 microgram tablet, 42**

| 11001B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 1717.71 | Adempas [BN] |

**riociguat 1.5 mg tablet, 42**

| 10989J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 1717.71 | Adempas [BN] |

## ▪ RIOCIGUAT

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 1 month following cessation of therapy, as recommended by the TGA-approved Product Information.

**Note** Special Pricing Arrangements apply.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR

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- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed Pulmonary Arterial Hypertension Initial PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed Pulmonary Arterial Hypertension Initial PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

HSD (Public)

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

HSD (Public)

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made two weeks prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 4 (Grandfathered patients)

**Clinical criteria:**

- Patient must have previously received treatment with this drug for this condition prior to 1 February 2017, **AND**
- Patient must be receiving treatment with this drug at the time of application, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have a documented history of WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have a documented history of WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a documented history of a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have a documented history of right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have a documented history of failure to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. The test results provided must not be more than 2 months old at the time of application.Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments;(2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approval for authority prescriptions will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 5 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Note** No applications for increased repeats will be authorised.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 5 (Grandfathered patients)

**Clinical criteria:**

- Patient must have previously received treatment with this drug for this condition prior to 1 February 2017, **AND**
- Patient must be receiving treatment with this drug at the time of application, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have a documented history of WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have a documented history of WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have a documented history of WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have a documented history of WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have a documented history of WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have a documented history of WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

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- Patient must have a documented history of WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. The test results provided must not be more than 2 months old at the time of application.Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments;(2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Approval for authority prescriptions will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 5 repeats.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Note** No applications for increased repeats will be authorised.

**riociguat 2 mg tablet, 84**

| 11039B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 3435.42 | Adempas [BN] |

**riociguat 1 mg tablet, 84**

| 11053R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 3435.42 | Adempas [BN] |

**riociguat 1 mg tablet, 42**

| 11054T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 1717.71 | Adempas [BN] |

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**riociguat 500 microgram tablet, 84**

| 11059C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 3435.42 | Adempas [BN] |

**riociguat 1.5 mg tablet, 84**

| 11048L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 3435.42 | Adempas [BN] |

**riociguat 2 mg tablet, 42**

| 11038Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 1717.71 | Adempas [BN] |

**riociguat 2.5 mg tablet, 84**

| 11024F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 3435.42 | Adempas [BN] |

**riociguat 2.5 mg tablet, 42**

| 11057Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 1717.71 | Adempas [BN] |

**riociguat 500 microgram tablet, 42**

| 11040C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 1717.71 | Adempas [BN] |

**riociguat 1.5 mg tablet, 42**

| 11047K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 1717.71 | Adempas [BN] |

HSD (Public)

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

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(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
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HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

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For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**

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- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

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An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**sildenafil 20 mg tablet, 90**

9547L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 319.72 | [a] APO-Sildenafil PHT [TX]<br>[a] Sildenafil AN PHT 20 [EA]<br>[a] Sildenafil Sandoz PHT 20 [SZ] | [a] Revatio [PF]<br>[a] SILDENAFIL-DRx [RZ] |

HSD (Public)

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

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(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
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**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

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A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
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**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
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Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

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(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
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Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

HSD (Public)

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**tadalafil 20 mg tablet, 56**

| 1308W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 796.60 | Adcirca [LY] |

# SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

## PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

### ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES

*Other anterior pituitary lobe hormones and analogues*

HSD (Public)

## PEGVISOMANT

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

**Authority required**

Acromegaly

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than 1.3 times upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.

Somatostatin analogues include octreotide, lanreotide and pasireotide

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

1) Growth hormone level greater than 2.5 mcg/L; and

2) IGF-1 level is greater than 1.3 times the age- and sex-adjusted ULN

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

The authority application must be made in writing and must include:

a) two completed authority prescription forms ; and

b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and

c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and

d) a recent result of the IGF-1 level and the date of assessment ; and

e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide

No increase in the maximum quantity or number of units may be authorised for the loading dose.

**pegvisomant 20 mg injection [1 vial] (&) inert substance diluent [1 syringe], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 11177G | 4 | .. | .. | *557.16 | Somavert [PF] |

## ▪ PEGVISOMANT

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Acromegaly

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than 1.3 times upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.

Somatostatin analogues include octreotide, lanreotide and pasireotide

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

1) Growth hormone level greater than 2.5 mcg/L; and

2) IGF-1 level is greater than 1.3 times the age- and sex-adjusted ULN

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

The authority application must be made in writing and must include:

a) two completed authority prescription forms ; and

b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and

c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and

d) a recent result of the IGF-1 level and the date of assessment ; and

e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide

No increase in the maximum quantity or number of units may be authorised for the loading dose.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
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Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Acromegaly

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition., **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue, **AND**
- The treatment must cease if IGF-1 is not lower after 3 months of pegvisomant treatment at the maximum tolerated dose.

Somatostatin analogues include octreotide, lanreotide and pasireotide

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

HSD (Public)

In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of IGF-1 level taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of application.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Acromegaly

Treatment Phase: Grandfathering

**Clinical criteria:**

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 September 2017, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue, **AND**
- Patient must have had a documented age- and sex- adjusted insulin- like factor 1 (IGF-1) concentration greater than 1.3 times upper limit of normal (ULN) prior to commencing non- PBS- subsidised treatment with this drug.

Somatostatin analogues include octreotide, lanreotide and pasireotide

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Treatment must be ceased if IGF-1 level is not lower after 3 months of pegvisomant treatment at the maximum tolerated dose.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Acromegaly Pegvisomant Grandfather PBS Authority Application - Supporting Information Form; and
3. in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and
4. a recent result of the IGF-1 level and the date of assessment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
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HOBART TAS 7001

**pegvisomant 10 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack**

| 11179J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 5 | .. | 4178.57 | Somavert [PF] |

**pegvisomant 15 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack**

| 11173C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 5 | .. | 4178.57 | Somavert [PF] |

**pegvisomant 20 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack**

| 11181L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 5 | .. | 4178.57 | Somavert [PF] |

## HYPOTHALAMIC HORMONES

*Somatostatin and analogues*

### ▪ LANREOTIDE

**Authority required (STREAMLINED)**

***7042***

Acromegaly

**Clinical criteria:**

- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; OR
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**

- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

**lanreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack**

5776B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 11 | .. | *1425.00 | Somatuline LA [IS] |

## ▪ LANREOTIDE

**Authority required (STREAMLINED)**

***7025***

Acromegaly

**Clinical criteria:**

- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; OR
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

**Authority required (STREAMLINED)**

***4575***

Functional carcinoid tumour

**Clinical criteria:**

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe**

5779E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 5 | .. | *4256.00 | Somatuline Autogel [IS] |

**lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe**

5778D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 5 | .. | *3401.00 | Somatuline Autogel [IS] |

**lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe**

5777C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 5 | .. | *2555.50 | Somatuline Autogel [IS] |

## ▪ OCTREOTIDE

**Authority required (STREAMLINED)**

***7029***

Acromegaly

**Clinical criteria:**

- The condition must be controlled with octreotide immediate release injections, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

**Authority required (STREAMLINED)**

HSD (Public)

***5901***
Functional carcinoid tumour
**Clinical criteria:**
- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.
**Authority required (STREAMLINED)**
***5906***
Vasoactive intestinal peptide secreting tumour (VIPoma)
**Clinical criteria:**
- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.



**octreotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

10533J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 5 | .. | *3479.62 | Sandostatin LAR [NV] |

**octreotide 10 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

10543X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 5 | .. | *2613.72 | Sandostatin LAR [NV] |

**octreotide 30 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

10550G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 5 | .. | *4354.92 | Sandostatin LAR [NV] |

## ▪ OCTREOTIDE

**Authority required (STREAMLINED)**
***7028***
Acromegaly
**Clinical criteria:**
- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; OR
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks, **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission
**Authority required (STREAMLINED)**
***6390***
Functional carcinoid tumour
**Clinical criteria:**
- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.
**Authority required (STREAMLINED)**
***6369***
Vasoactive intestinal peptide secreting tumour (VIPoma)
**Clinical criteria:**
- The condition must be causing intractable symptoms, **AND**

- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**octreotide 50 microgram/mL injection, 5 x 1 mL ampoules**

| 9508K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 18 | 11 | .. | *619.02 | [a] Hospira Pty Limited [PF]<br>[a] Octreotide (SUN) [RA] | [a] Octreotide MaxRx [GQ]<br>[a] Sandostatin 0.05 [NV] |

**octreotide 500 microgram/mL injection, 5 x 1 mL ampoules**

| 9510M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 18 | 11 | .. | *6194.52 | [a] Hospira Pty Limited [PF]<br>[a] Octreotide (SUN) [RA] | [a] Octreotide MaxRx [GQ]<br>[a] Sandostatin 0.5 [NV] |

**octreotide 100 microgram/mL injection, 5 x 1 mL ampoules**

| 9509L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 18 | 11 | .. | *1236.42 | [a] Hospira Pty Limited [PF]<br>[a] Octreotide (SUN) [RA] | [a] Octreotide MaxRx [GQ]<br>[a] Sandostatin 0.1 [NV] |

HSD (Public)

## ▪ PASIREOTIDE

**Caution** Careful monitoring of patients is mandatory due to high risk of developing hyperglycaemia

**Note** Special Pricing Arrangements apply.

**Authority required**

Acromegaly

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a mean growth hormone (GH) level greater than 2.5 micrograms per litre, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) level greater than 1.3 times the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

**Population criteria:**

- Patient must be aged 18 years or older.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

Failure to achieve biochemical control is defined as:

1) Growth hormone level is greater than 2.5 mcg/L; and

2) IGF-1 level is greater than 1.3 times the age- and sex-adjusted ULN

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

1) Growth hormone (GH) levels of less than 2.5 mcg/L; and

2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

The authority application must be made in writing and must include:

a) a completed authority prescription form; and

b) a completed Acromegaly PBS Authority Application - Supporting Information Form; and

c) a signed patient acknowledgment; and

d) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided; and

e) a recent copy of GH and IGF-1 levels must be provided.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

**Authority required**

Acromegaly

Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- Patient must have received non-PBS treatment with this drug for this condition prior to 1 September 2016.

**Population criteria:**

- Patient must be aged 18 years or older.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

1) Growth hormone (GH) levels of less than 2.5 mcg/L; and

2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

The authority application must be made in writing and must include:

a) a completed authority prescription form; and

b) a completed Acromegaly PBS Authority Application - Supporting Information Form; and

c) a signed patient acknowledgment; and

d) in a patient who has previously been treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Acromegaly

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

**Population criteria:**

- Patient must be aged 18 years or older.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

1) Growth hormone (GH) levels of less than 2.5 mcg/L; and

2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy and the GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of approval.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**pasireotide 60 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

10882R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 5 | .. | *7800.00 | Signifor LAR [NV] |

**pasireotide 40 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

10883T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 5 | .. | *7800.00 | Signifor LAR [NV] |

**pasireotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

10886Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 5 | .. | *7800.00 | Signifor LAR [NV] |

# ANTIINFECTIVES FOR SYSTEMIC USE

## ANTIBACTERIALS FOR SYSTEMIC USE

### MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

*Macrolides*

#### AZITHROMYCIN

**Authority required (STREAMLINED)**

***6356***

Mycobacterium avium complex infection

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be human immunodeficiency virus (HIV) positive, **AND**
- Patient must have CD4 cell counts of less than 75 per cubic millimetre.

**azithromycin 600 mg tablet, 8**

5616N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 5 | .. | *110.76 | Zithromax [PF] |

#### CLARITHROMYCIN

**Authority required (STREAMLINED)**

***5874***

Mycobacterium avium complex infection

**clarithromycin 500 mg tablet, 100**

5624B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 2 | .. | 31.33 | APO-Clarithromycin [TX] |

## ANTIMYCOBACTERIALS

### DRUGS FOR TREATMENT OF TUBERCULOSIS

*Antibiotics*

#### RIFABUTIN

**Authority required (STREAMLINED)**

***6350***

Mycobacterium avium complex infection

**Clinical criteria:**

- Patient must be human immunodeficiency virus (HIV) positive.

**Authority required (STREAMLINED)**

***6356***

Mycobacterium avium complex infection

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be human immunodeficiency virus (HIV) positive, **AND**
- Patient must have CD4 cell counts of less than 75 per cubic millimetre.

**rifabutin 150 mg capsule, 30**

9541E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 4 | 5 | .. | *615.00 | Mycobutin [PF] |

## ANTIVIRALS FOR SYSTEMIC USE

### DIRECT ACTING ANTIVIRALS

*Nucleosides and nucleotides excl. reverse transcriptase inhibitors*

#### GANCICLOVIR

**Authority required (STREAMLINED)**

***4972***

Cytomegalovirus disease

Treatment Phase: Prophylaxis

**Clinical criteria:**

- Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.

**Authority required (STREAMLINED)**

***4999***

Cytomegalovirus disease

Treatment Phase: Prophylaxis

**Clinical criteria:**

- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

**ganciclovir 500 mg injection, 5 vials**

| 5749N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 1 | .. | *532.00 | Cymevene [RO] |

## ▪ RIBAVIRIN

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**Population criteria:**

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**ribavirin 400 mg tablet, 28**

| 10646H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 5 | .. | 140.00 | Ibavyr [IX] |

**ribavirin 200 mg tablet, 28**

| 10914K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 5 | .. | 70.00 | Ibavyr [IX] |

**ribavirin 600 mg tablet, 28**

| 10638X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 5 | .. | 210.00 | Ibavyr [IX] |

## ▪ RIBAVIRIN

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**Population criteria:**

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**ribavirin 400 mg tablet, 28**

| 10678B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 2 | .. | 140.00 | Ibavyr [IX] |

**ribavirin 200 mg tablet, 28**

| 10929F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 2 | .. | 70.00 | Ibavyr [IX] |

**ribavirin 600 mg tablet, 28**

| 10663F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 2 | .. | 210.00 | Ibavyr [IX] |

## ▪ VALACICLOVIR

**Authority required (STREAMLINED)**

***5975***

Cytomegalovirus infection and disease

HSD (Public)

Treatment Phase: Prophylaxis

**Clinical criteria:**

- Patient must have undergone a renal transplant, **AND**
- Patient must be at risk of cytomegalovirus disease.

**valaciclovir 500 mg tablet, 100**

| 9568N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 5 | 2 | .. | *221.00 | [a] APO-Valaciclovir [TX] | [a] Valaciclovir RBX [RA] |
| | | | [B]2.20 | *223.20 | [a] Valtrex [RW] | |

## ▪ VALGANCICLOVIR

**Authority required (STREAMLINED)**

***4989***

Cytomegalovirus infection and disease

Treatment Phase: Prophylaxis

**Clinical criteria:**

- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

**valganciclovir 50 mg/mL powder for oral liquid, 100 mL**

| 9655E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 11 | 5 | .. | *4346.10 | Valcyte [RO] |

**valganciclovir 450 mg tablet, 60**

| 9569P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *3584.30 | [a] Valcyte [RO] | [a] Valganciclovir AN [EA] |
| | | | | | [a] Valganciclovir Juno [JU] | [a] Valganciclovir Mylan [AF] |
| | | | | | [a] Valganciclovir Sandoz [SZ] | |

*Other antivirals*

## ▪ DACLATASVIR

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**daclatasvir 60 mg tablet, 28**

| 10641C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 5 | .. | 7666.67 | Daklinza [BQ] |

**daclatasvir 30 mg tablet, 28**

| 10629K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 5 | .. | 7666.67 | Daklinza [BQ] |

## ▪ DACLATASVIR

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**daclatasvir 60 mg tablet, 28**

| 10660C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 2 | .. | 7666.67 | Daklinza [BQ] |

**daclatasvir 30 mg tablet, 28**

| 10651N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 2 | .. | 7666.67 | Daklinza [BQ] |

## ▪ GRAZOPREVIR + ELBASVIR

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**
Chronic hepatitis C infection
**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**grazoprevir 100 mg + elbasvir 50 mg tablet, 28**

| 10978T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 2 | .. | 21000.00 | Zepatier [MK] |



## ▪ GRAZOPREVIR + ELBASVIR

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**
Chronic hepatitis C infection
**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

**grazoprevir 100 mg + elbasvir 50 mg tablet, 28**

| 10986F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 3 | .. | 21000.00 | Zepatier [MK] |

## ▪ LEDIPASVIR + SOFOSBUVIR

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**
Chronic hepatitis C infection
**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28**

| 10661D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 2 | .. | 22066.67 | Harvoni [GI] |

## ▪ LEDIPASVIR + SOFOSBUVIR

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**
Chronic hepatitis C infection
**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 8 weeks.

**ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10667K | 1 | 1 | .. | 22066.67 | Harvoni [GI] |

## ▪ LEDIPASVIR + SOFOSBUVIR

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10669M | 1 | 5 | .. | 22066.67 | Harvoni [GI] |

## ▪ PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56], 4 x 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10751W | 1 | 2 | .. | 13853.13 | Viekira Pak [VE] |

## ▪ PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR & RIBAVIRIN

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**Population criteria:**

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 600 mg tablet [56], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10768R | 1 | 5 | .. | 13853.13 | Viekira Pak-RBV [VE] |

**paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 200 mg tablet [168], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10752X | 1 | 5 | .. | 13853.13 | Viekira Pak-RBV [VE] |

## ▪ PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR & RIBAVIRIN

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**Population criteria:**

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 600 mg tablet [56], 1 pack**

10754B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 2 | .. | 13853.13 | Viekira Pak-RBV [VE] |

**paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 200 mg tablet [168], 1 pack**

10765N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 2 | .. | 13853.13 | Viekira Pak-RBV [VE] |

## ▪ SOFOSBUVIR

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**sofosbuvir 400 mg tablet, 28**

10625F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 2 | .. | 19297.75 | Sovaldi [GI] |

## ▪ SOFOSBUVIR

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**sofosbuvir 400 mg tablet, 28**

10648K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 5 | .. | 19297.75 | Sovaldi [GI] |

## ▪ SOFOSBUVIR + VELPATASVIR

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

HSD (Public)

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**sofosbuvir 400 mg + velpatasvir 100 mg tablet, 28**

| 11145N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 2 | .. | 22066.67 | Epclusa [GI] |

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

## ANTINEOPLASTIC AGENTS

### ANTIMETABOLITES

*Pyrimidine analogues*

## AZACITIDINE

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Myelodysplastic syndrome

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR
- The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS).

Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:

a. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR

b. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR

c. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR

d. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR

e. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR

f. Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

a. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR

b. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR

c. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR

d. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

The first authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and

(c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and

(d) a copy of the full blood examination report; and

(e) a copy of the pathology report detailing the cytogenetics demonstrating intermediate-2 or high risk disease according to the International Prognostic Scoring System (IPSS); and

(f) a signed patient acknowledgment form.

No more than 3 cycles will be authorised.

**Authority required**

Chronic Myelomonocytic Leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder.

HSD (Public)

The first authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and
(c) a copy of the bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia ; and
(d) a copy of the full blood examination report; and
(e) a signed patient acknowledgement.
No more than 3 cycles will be authorised.

**Authority required**

Acute Myeloid Leukaemia
Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

The first authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and
(c) a copy of the bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and
(d) a copy of the full blood examination report; and
(e) a signed patient acknowledgement.
No more than 3 cycles will be authorised.

HSD (Public)

**azacitidine 100 mg injection, 1 vial**

9597D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 14 | 2 | .. | *5172.16 | [a] Azacitidine Accord [OC]<br>[a] Azadine [RZ]<br>[a] Vidaza [CJ] | [a] AZACITIDINE DR.REDDY'S [RI]<br>[a] Celazadine [JU] |

## ▪ AZACITIDINE

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Myelodysplastic syndrome
Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR
- The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.
Up to 6 cycles will be authorised.

**Authority required**

Chronic Myelomonocytic Leukaemia
Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.
Up to 6 cycles will be authorised.

**Authority required**

Acute Myeloid Leukaemia
Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.
Up to 6 cycles will be authorised.

**azacitidine 100 mg injection, 1 vial**

9598E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 14 | 5 | .. | *5172.16 | [a] Azacitidine Accord [OC]<br>[a] Azadine [RZ]<br>[a] Vidaza [CJ] | [a] AZACITIDINE DR.REDDY'S [RI]<br>[a] Celazadine [JU] |

## CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

*Anthracyclines and related substances*

### ▪ DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL

**Authority required (STREAMLINED)**

***6234***

Kaposi sarcoma

**Clinical criteria:**

- The condition must be AIDS-related, **AND**
- Patient must have a CD4 cell count of less than 200 per cubic millimetre, **AND**
- The condition must include extensive mucocutaneous involvement.

**Authority required (STREAMLINED)**

***6274***

Kaposi sarcoma

**Clinical criteria:**

- The condition must be AIDS-related, **AND**
- Patient must have a CD4 cell count of less than 200 per cubic millimetre, **AND**
- The condition must include extensive visceral involvement.

**doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial**

5705G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 5 | .. | *1059.20 | [a] Caelyx [JC] | [a] Liposomal Doxorubicin SUN [RA] |

## OTHER ANTINEOPLASTIC AGENTS

*Monoclonal antibodies*

### ▪ RITUXIMAB

**Note** Risk of end-organ damage or mortality includes a minimum of one of the following:Glomerulonephritis with risk of progression

- Risk to sight including scleritis/episcleritis, sudden visual loss, uveitis, retinal changes (vasculitis/thrombosis/exudates/haemorrhage)
- Bronchial/subglottic obstruction
- Pulmonary haemorrhage
- Parenchymal lung disease
- Sensory neural hearing loss
- Recurrent sinonasal disease requiring recurrent surgical interventions
- Meningitis, organic confusion, seizures, stroke, cord lesion, cranial nerve palsy, sensory peripheral neuropathy, motor mononeuritis multiplex

**Note** Patients could be considered contraindicated, refractory, or unable to tolerate cyclophosphamide for one of the following reasons: Cyclophosphamide is contraindicated as per the TGA approved Product Information;

- Cyclophosphamide is not recommended due to the need to preserve gonad function;
- Patient experiences severe toxicity to cyclophosphamide that warrants cessation of treatment;
- Patient has life- or organ-threatening deterioration at any time during treatment with cyclophosphamide, where the deterioration is thought to be due to severe uncontrolled active vasculitis;
- Commencing a further treatment cycle with cyclophosphamide would exceed the maximum cumulative dose of cyclophosphamide of 25g; or
- Patient's condition with this indication is persistent despite at least 3 months therapy with cyclophosphamide.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment.

**Authority required**

Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)

Treatment Phase: Induction of remission

**Clinical criteria:**

- The treatment must be for the induction of remission, **AND**
- Patient must not have previously received this drug for this condition; OR
- Patient must have received this drug for this condition prior to 1 January 2016, **AND**
- The treatment must in combination with glucocorticoids, **AND**

- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance of remission

The authority application must be made in writing

**Authority required**

Severe active microscopic polyangiitis

Treatment Phase: Induction of remission

**Clinical criteria:**

- The treatment must be for the induction of remission, **AND**
- Patient must not have previously received this drug for this condition; OR
- Patient must have received this drug for this condition prior to 1 January 2016, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance therapy.

The authority application must be made in writing

**Authority required**

Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)

Treatment Phase: Re-induction of remission

**Clinical criteria:**

- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance of remission

The authority application must be made in writing

**Authority required**

Severe active microscopic polyangiitis

Treatment Phase: Re-induction of remission

**Clinical criteria:**

- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance therapy.

The authority application must be made in writing

**rituximab 100 mg/10 mL injection, 2 x 10 mL vials**

10591K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 745.70 | Mabthera [RO] |

**rituximab 500 mg/50 mL injection, 50 mL vial**

10593M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 1864.22 | Mabthera [RO] |

## ▪ IMMUNOSTIMULANTS

### IMMUNOSTIMULANTS

*Colony stimulating factors*

### ▪ FILGRASTIM

**Authority required (STREAMLINED)**

***6544***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be undergoing induction or consolidation therapy for acute myeloid leukaemia.

**Authority required (STREAMLINED)**

***6522***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

***6545***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must must be receiving chemotherapy with fludarabine and cyclophosphamide for B-cell chronic lymphocytic leukaemia, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

***6532***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving first-line chemotherapy for Hodgkin disease, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

***6515***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy for myeloma, **AND**
- Patient must have had a prior episode of febrile neutropenia, **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

***6492***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil for inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

***6507***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

**Authority required (STREAMLINED)**

***6533***

Chemotherapy-induced neutropenia

**Clinical criteria:**

HSD (Public)

- Patient must be receiving treatment with aggressive chemotherapy (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide) with the intention of achieving a cure or substantial remission in breast cancer.

**Authority required (STREAMLINED)**

***6523***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

**Authority required (STREAMLINED)**

***6534***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen).

**Authority required (STREAMLINED)**

***6535***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

**Authority required (STREAMLINED)**

***6536***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma.

**Authority required (STREAMLINED)**

***6493***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy (first-line chemotherapy with escalated BEACOPP) with the intention of achieving a cure or substantial remission in Hodgkin disease.

**Authority required (STREAMLINED)**

***6502***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in an infant or child with central nervous system tumours.

**Authority required (STREAMLINED)**

***6516***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma.

**Authority required (STREAMLINED)**

***6653***

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

**Authority required (STREAMLINED)**

***6654***

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

**Authority required (STREAMLINED)**

***6679***

Assisting bone marrow transplantation

**Clinical criteria:**

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

**Authority required (STREAMLINED)**

***6655***

Assisting autologous peripheral blood progenitor cell transplantation

**Clinical criteria:**

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

**Authority required (STREAMLINED)**

***6680***

HSD (Public)

Severe congenital neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

**Authority required (STREAMLINED)**

***6621***

Severe chronic neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

**Authority required (STREAMLINED)**

***6640***

Chronic cyclical neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

**filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes**

| 2758E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 4 | 11 | .. | *914.36 | Zarzio [SZ] |

**filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes**

| 5829T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 11 | .. | *365.74 | Nivestim [PF] |

**filgrastim 300 microgram/mL injection, 10 x 1 mL vials**

| 5741E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 11 | .. | *914.36 | Neupogen [AN] |

**filgrastim 480 microgram/1.6 mL injection, 10 x 1.6 mL vials**

| 5743G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 11 | .. | *1465.78 | Neupogen [AN] |

**filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes**

| 2783L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 4 | 11 | .. | *1465.76 | Zarzio [SZ] |

**filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes**

| 5744H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 11 | .. | *1465.78 | Neupogen [AN] |

**filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes**

| 9694F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 11 | .. | *1465.78 | Nivestim [PF] |

**filgrastim 480 microgram/0.8 mL injection, 10 x 0.8 mL syringes**

| 1126G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 11 | .. | *1465.78 | TevaGrastim [TB] |

**filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes**

| 1123D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 11 | .. | *914.36 | TevaGrastim [TB] |

**filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes**

| 5742F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 11 | .. | *914.36 | Neupogen [AN] |

HSD (Public)

**filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes**

9692D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 11 | .. | *914.36 | Nivestim [PF] |

## ▪ LENOGRASTIM

**Authority required (STREAMLINED)**

***6522***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

***6532***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving first-line chemotherapy for Hodgkin disease, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

***6507***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

**Authority required (STREAMLINED)**

***6523***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

**Authority required (STREAMLINED)**

***6535***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

**Authority required (STREAMLINED)**

***6502***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in an infant or child with central nervous system tumours.

**Authority required (STREAMLINED)**

***6516***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma.

**Authority required (STREAMLINED)**

***6644***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Ewing's sarcoma.

**Authority required (STREAMLINED)**

***6673***

Chemotherapy-induced neutropenia

**Clinical criteria:**

HSD (Public)

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin's lymphoma (intermediate or high grade).

**Authority required (STREAMLINED)**

***6634***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in osteosarcoma.

**Authority required (STREAMLINED)**

***6682***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in rhabdomyosarcoma.

**Authority required (STREAMLINED)**

***6653***

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

**Authority required (STREAMLINED)**

***6654***

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

**Authority required (STREAMLINED)**

***6657***

Assisting peripheral blood progenitor cell or bone marrow transplantation

**Clinical criteria:**

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

**LENOGRASTIM Powder for injection 13,400,000 i.u. (105 micrograms) vial, 10**

5787N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 11 | .. | *973.76 | Granocyte 13 [PF] |

**LENOGRASTIM Powder for injection 33,600,000 i.u. (263 micrograms) vial, 10**

5788P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 11 | .. | *2438.84 | Granocyte 34 [PF] |

## ▪ LIPEGFILGRASTIM

**Authority required (STREAMLINED)**

***6522***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

***6544***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be undergoing induction or consolidation therapy for acute myeloid leukaemia.

**Authority required (STREAMLINED)**

***6545***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must must be receiving chemotherapy with fludarabine and cyclophosphamide for B-cell chronic lymphocytic leukaemia, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**

HSD (Public)

- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

***6532***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving first-line chemotherapy for Hodgkin disease, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

***6515***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy for myeloma, **AND**
- Patient must have had a prior episode of febrile neutropenia, **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

***6492***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil for inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

***6507***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

**Authority required (STREAMLINED)**

***6533***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide) with the intention of achieving a cure or substantial remission in breast cancer.

**Authority required (STREAMLINED)**

***6523***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

**Authority required (STREAMLINED)**

***6534***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen).

**Authority required (STREAMLINED)**

***6535***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

**Authority required (STREAMLINED)**

***6536***

Chemotherapy-induced neutropenia

HSD (Public)

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma.

**Authority required (STREAMLINED)**

***6493***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy (first-line chemotherapy with escalated BEACOPP) with the intention of achieving a cure or substantial remission in Hodgkin disease.

**lipegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe**

10936N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 11 | .. | 1250.00 | Lonquex [TB] |

## ▪ PEGFILGRASTIM

**Authority required (STREAMLINED)**

***6544***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be undergoing induction or consolidation therapy for acute myeloid leukaemia.

**Authority required (STREAMLINED)**

***6522***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

***6545***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must must be receiving chemotherapy with fludarabine and cyclophosphamide for B-cell chronic lymphocytic leukaemia, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

***6532***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving first-line chemotherapy for Hodgkin disease, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

***6515***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy for myeloma, **AND**
- Patient must have had a prior episode of febrile neutropenia, **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

***6492***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil for inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

***6507***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

**Authority required (STREAMLINED)**

***6533***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide) with the intention of achieving a cure or substantial remission in breast cancer.

**Authority required (STREAMLINED)**

***6523***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

**Authority required (STREAMLINED)**

***6534***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen).

**Authority required (STREAMLINED)**

***6535***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

**Authority required (STREAMLINED)**

***6536***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma.

**Authority required (STREAMLINED)**

***6493***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy (first-line chemotherapy with escalated BEACOPP) with the intention of achieving a cure or substantial remission in Hodgkin disease.

**Authority required (STREAMLINED)**

***6502***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in an infant or child with central nervous system tumours.

**Authority required (STREAMLINED)**

***6516***

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma.

**pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe**

9514R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 11 | .. | 1250.00 | [a] Neulasta [AN] | [a] Ristempa [GV] |

*Interferons*

## ▪ INTERFERON ALFA-2A

**Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required (STREAMLINED)**

***5042***

Chronic Myeloid Leukaemia (CML)

**Clinical criteria:**

- The condition must be Philadelphia chromosome positive.

**interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5759D | 30 | 5 | .. | *849.30 | Roferon-A [RO] |

**interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5762G | 30 | 5 | .. | *2547.30 | Roferon-A [RO] |

## ▪ INTERFERON ALFA-2B

**Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required (STREAMLINED)**

***5042***

Chronic Myeloid Leukaemia (CML)

**Clinical criteria:**

- The condition must be Philadelphia chromosome positive.

**Authority required (STREAMLINED)**

***4974***

Malignant melanoma

**Clinical criteria:**

- The treatment must be as adjunctive therapy to current standard care, **AND**
- Patient must have undergone surgery, **AND**
- The condition must include nodal involvement.

**interferon alfa-2b 30 million units/1.2 mL injection, 1.2 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5764J | 2 | 5 | .. | *566.02 | Intron A Redipen [MK] |

**interferon alfa-2b 60 million units/1.2 mL injection, 1.2 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5765K | 2 | 5 | .. | *1132.02 | Intron A Redipen [MK] |

**interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5763H | 2 | 5 | .. | *339.60 | Intron A Redipen [MK] |

**interferon alfa-2b 18 million units/3 mL injection, 3 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5766L | 15 | 5 | .. | *2547.00 | Intron A [MK] |

**interferon alfa-2b 10 million units/mL injection, 5 x 1 mL vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5768N | 3 | 5 | .. | *1415.04 | Intron A [MK] |

**interferon alfa-2b 25 million units/2.5 mL injection, 2.5 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5767M | 15 | 5 | .. | *3537.60 | Intron A [MK] |

## ▪ INTERFERON GAMMA-1B

**Authority required (STREAMLINED)**

***6222***

Chronic granulomatous disease

**Clinical criteria:**

- Patient must have frequent and severe infections despite adequate prophylaxis with antimicrobial agents.

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**interferon gamma-1b 2 million units (100 microgram)/0.5 mL injection, 6 x 0.5 mL vials**

5769P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 11 | .. | *2585.72 | Imukin [BY] |

## ▪ PEGINTERFERON ALFA-2A

**Caution** Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Note** Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

**Authority required (STREAMLINED)**

***5004***

Chronic hepatitis C infection

**Treatment criteria:**

- Must be treated in an accredited treatment centre.

**Population criteria:**

- Patient must be aged 18 years or older, **AND**
- Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age.

**Clinical criteria:**

- Patient must have compensated liver disease, **AND**
- Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, **AND**
- Patient must have a contraindication to ribavirin, **AND**
- The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, **AND**
- The treatment must be limited to a maximum duration of 48 weeks.

Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

**peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

9516W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 5 | .. | *2565.44 | Pegasys [RO] |

**peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

9515T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 5 | .. | *2215.22 | Pegasys [RO] |

## ▪ PEGINTERFERON ALFA-2A

**Caution** Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

11026H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 2 | .. | 1282.72 | Pegasys [RO] |

*Other immunostimulants*

## ▪ PLERIXAFOR

**Note** Applications for increased maximum quantities will only be authorised for patients with body weight greater than 100 kg.

**Authority required (STREAMLINED)**

***4549***

Mobilisation of haematopoietic stem cells

**Clinical criteria:**

- The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF), **AND**
- Patient must have lymphoma; OR
- Patient must have multiple myeloma, **AND**
- Patient must require autologous stem cell transplantation, **AND**
- Patient must have failed previous stem cell collection; OR
- Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; OR
- Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

**plerixafor 24 mg/1.2 mL subcutaneous infusion injection, 1.2 mL vial**

| 10083Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 1 | .. | 6991.00 | Mozobil [GZ] |

# IMMUNOSUPPRESSANTS

## IMMUNOSUPPRESSANTS

*Selective immunosuppressants*

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### ABATACEPT

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-

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subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when

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commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

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AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For

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these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
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**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most

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recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**abatacept 250 mg injection, 1 vial**

5605B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 266.34 | Orencia [BQ] |

## ▪ ALEMTUZUMAB

**Note** Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.
**Note** Special Pricing Arrangements apply.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**
***6847***
Multiple sclerosis
Treatment Phase: Continuing treatment
**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Treatment criteria:**

- Must be treated by a neurologist.

**alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial**

10232M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 3 | .. | .. | *34182.00 | Lemtrada [GZ] |

## ▪ ALEMTUZUMAB

**Note** Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.
**Note** Special Pricing Arrangements apply.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**
***6884***
Multiple sclerosis
Treatment Phase: Initial treatment
**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial**

10228H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 5 | .. | .. | *56970.00 | Lemtrada [GZ] |

## ▪ ECULIZUMAB

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 4 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.
**Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.
**Note** Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:
a) Active malignancy;
b) Active HIV infection;
c) Hematopoietic stem cell transplants;
d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
f) Active autoimmune diseases;
In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.
**Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:
a) Presenting clinical features, including history, acute treatment and medications;

HSD (Public)

b) Results of testing for genetic mutations (if available);
c) Family history of aHUS, especially in first-degree relatives;
d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;
e) Exclusion of alternative causes of TMA;
f) History of renal or other organ transplant (if any);
g) Any other matters considered relevant by the prescriber.
In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

**Note** The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment - Balance of Supply

**Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

**Clinical criteria:**

- Patient must have received PBS-subsidised initial supply of eculizumab for this condition, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample, **AND**
- Patient must not receive more than 20 weeks supply under this restriction.

ADAMTS-13 activity result must have been submitted to the Department of Human Services. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for **Initial Treatment,** ADAMTS-13 activity must have been measured 1-2 weeks following the last plasma exchange or infusion, and must have been submitted to the Department of Human Services within 27 days of commencement of eculizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the two weeks prior to collection of the ADAMTS-13 assay must also have been provided to Department of Human Services.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

**eculizumab 300 mg/30 mL injection, 30 mL vial**

| 10190H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 4 | .. | 5937.50 | Soliris [XI] |

## ▪ ECULIZUMAB

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment, according to the specified dosage in the approved Product Information (PI).
Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis).
Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:
a) Active malignancy;
b) Active HIV infection;
c) Hematopoietic stem cell transplants;
d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
f) Active autoimmune diseases;
In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

**Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:
a) Presenting clinical features, including history, acute treatment and medications;
b) Results of testing for genetic mutations (if available);
c) Family history of aHUS, especially in first-degree relatives;
d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;
e) Exclusion of alternative causes of TMA;
f) History of renal or other organ transplant (if any);
g) Any other matters considered relevant by the prescriber.
In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

HSD (Public)

**Note** The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

HSD (Public)

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have active and progressing thrombotic microangiopathy (TMA) caused by aHUS, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than 30x10^9/L and a serum creatinine of greater than 150 mol/L, **AND**
- Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days, **AND**
- Patient must have clinical features of active organ damage or impairment, **AND**
- Patient must not receive more than 4 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Evidence of active and progressing TMA is defined by the following:

(1) a platelet count of less than 150x10^9/L; and evidence of two of the following:

(i) presence of schistocytes on blood film;

(ii) low or absent haptoglobin;

(iii) lactate dehydrogenase (LDH) above normal range;

OR

(2) in recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; AND

(3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one of the following:

(i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or

(ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or

(iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or

(iv) a renal biopsy consistent with aHUS;

(b) onset of TMA-related neurological impairment;

(c) onset of TMA-related cardiac impairment;

(d) onset of TMA-related gastrointestinal impairment;

(e) onset of TMA-related pulmonary impairment.

Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised eculizumab (where possible), and should be supported by objective clinical measures. The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form - Initial PBS-subsidised eculizumab treatment; and

(3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and

(4) A detailed cover letter from the prescriber; and

(5) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and

(6) A measurement of body weight at the time of application; and

(7) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay; and

(8) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 1-2 weeks following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to the Department of Human Services within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under **Initial treatment 1-balance of supply**; and

(9) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days; and

(10) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within one month of application; and

(11) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.

**eculizumab 300 mg/30 mL injection, 30 mL vial**

10191J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 5937.50 | Soliris [XI] |

## ▪ ECULIZUMAB

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 6 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note** For patients who have received continuing treatment with PBS-subsidised eculizumab prior to 1 January 2016, this restriction is limited to 28 weeks of therapy.

**Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:
a) Active malignancy;
b) Active HIV infection;
c) Hematopoietic stem cell transplants;
d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
f) Active autoimmune diseases;
In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

**Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:
a) Presenting clinical features, including history, acute treatment and medications;
b) Results of testing for genetic mutations (if available);
c) Family history of aHUS, especially in first-degree relatives;
d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;
e) Exclusion of alternative causes of TMA;
f) History of renal or other organ transplant (if any);
g) Any other matters considered relevant by the prescriber.
In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

**Note** The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended initial treatment - Assessment phase

**Clinical criteria:**

- Patient must have received treatment under the initial restriction with PBS subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must not receive more than 56 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

HSD (Public)

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure.

A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

A maximum of up to 56 weeks of treatment is allowed under this restriction, however an application must be submitted at 6 months, 12 months, 18 months and 24 months following commencing PBS-subsidised eculizumab.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Extended Initial treatment; and

(3) A detailed cover letter from the prescriber; and

(4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and

(5) A measurement of body weight at the time of application; and

(6) An identified genetic mutation, if applicable; and

(7) A family history of aHUS, if applicable; and

(8) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and

(9) A history of kidney transplant, if applicable, (especially if required due to aHUS); and

(10) An inclusion of the individual consequences of recurrent disease, if applicable; and

(11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and

(12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

**eculizumab 300 mg/30 mL injection, 30 mL vial**

10525Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 6 | .. | 5937.50 | Soliris [XI] |

## ▪ ECULIZUMAB

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:

a) Active malignancy;
b) Active HIV infection;
c) Hematopoietic stem cell transplants;
d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
f) Active autoimmune diseases;

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

**Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

a) Presenting clinical features, including history, acute treatment and medications;
b) Results of testing for genetic mutations (if available);
c) Family history of aHUS, especially in first-degree relatives;
d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;
e) Exclusion of alternative causes of TMA;
f) History of renal or other organ transplant (if any);
g) Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

**Note** The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

HSD (Public)

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received treatment under Extended Initial restriction with PBS subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure.

A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and

(3) A detailed cover letter from the prescriber; and

(4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and

(5) A measurement of body weight at the time of application; and

(6) An identified genetic mutation, if applicable; and

(7) A family history of aHUS, if applicable; and

(8) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and

(9) A history of kidney transplant if applicable (especially if required due to aHUS); and

(10) An inclusion of the individual consequences of recurrent disease, if applicable; and

(11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and

(12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended Continuing treatment

**Clinical criteria:**

- Patient must have received treatment under the Continuing treatment with PBS-subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**

- Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40% on current objective measurement; OR
- Patient must have severe TMA-related neurological impairment; OR
- Patient must have severe TMA-related gastrointestinal impairment; OR
- Patient must have severe TMA-related pulmonary impairment on current objective measurement; OR
- Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 mL/min); OR
- Patient must have a high risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and

(3) A detailed cover letter from the prescriber; and

(4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and

(5) A measurement of body weight at the time of application; and

(6) An identified genetic mutation, if applicable; and

(7) A family history of aHUS, if applicable; and

(8) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and

(9) A history of kidney transplant, if applicable (especially if required due to aHUS); and

(10) An inclusion of the individual consequences of recurrent disease; and

(11) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment; and

(12) Evidence that the patient has had a treatment response including haematological results of no more than 1 month old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 month old at the time of application; and

(13) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(14) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

**Note** All applications should be accompanied by a detailed letter that outlines the objective evidence of high risk of critical organ damage if aHUS recurs. The following evidence may be submitted to establish the patient's level of risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab:
a) Evidence of a mutation known to confer a high risk of aHUS recurrence;
b) Past history of recurrent episodes of active and progressive TMA due to aHUS, prior to the episode that led to current use of eculizumab;
c) Past family history of aHUS recurrence, especially in first-degree relatives;
d) Past history of recurrent aHUS following renal transplant for end-stage renal failure due to aHUS.

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**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have demonstrated treatment response to previous treatment with PBS-subsidised eculizumab for this condition, **AND**

HSD (Public)

- Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must have the following clinical conditions:(i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal;AND(ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count <150 x 10^9/L);OR(iii) TMA-related organ impairment including on recent biopsy, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form(s); and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Recommencement of treatment; and

(3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and

(4) A detailed cover letter from the prescriber; and

(5) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and

(6) A measurement of body weight at the time of application, and

(7) An identified genetic mutation, if applicable; and

(8) A family history of aHUS if applicable; and

(9) A history of multiple episodes of aHUS following the treatment break, if applicable; and

(10) A history of kidney transplant if applicable (especially if required due to aHUS); and

(11) An inclusion of the individual consequences of recurrent disease; and

(12) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;

(13) Evidence that the patient has had a treatment response to their previous treatment with eculizumab; and

(14) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(15) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

**Note** A raise in LDH alone is not a sufficient reason to re-commence eculizumab, but thrombocytopenia with one marker of haemolysis (such as raised LDH, presence of schistocytes, or low/absence of haptoglobin) is an accepted reason to consider re-commencement of eculizumab treatment.

**Note** Kidney transplantation/dialysis is not a contraindication to recommencement of eculizumab treatment.

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**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing recommencement of treatment

**Clinical criteria:**

- Patient must have received treatment under Recommencement of treatment restriction with PBS-subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated ongoing treatment response to the previous 24 weeks of PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

HSD (Public)

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and

(3) A detailed cover letter from the prescriber; and

(4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and

(5) A measurement of body weight at the time of application; and

(6) An identified genetic mutation, if applicable; and

(7) A family history of aHUS, if applicable; and

(8) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and

(9) A history of kidney transplant if applicable (especially if required due to aHUS); and

(10) An inclusion of the individual consequences of recurrent disease, if applicable; and

(11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and

(12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

**eculizumab 300 mg/30 mL injection, 30 mL vial**

10183Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 5 | .. | 5937.50 | Soliris [XI] |

## ▪ EVEROLIMUS

**Caution** Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)**

***5795***

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**Authority required (STREAMLINED)**

***5554***

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**everolimus 750 microgram tablet, 60**

5740D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 4 | 5 | .. | *2739.44 | Certican [NV] |

**everolimus 1 mg tablet, 60**

5737Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 4 | 5 | .. | *3652.56 | Certican [NV] |

**everolimus 500 microgram tablet, 60**

| 5739C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *913.14 | Certican [NV] |

**everolimus 250 microgram tablet, 60**

| 5738B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *456.58 | Certican [NV] |

## ▪ MYCOPHENOLATE

**Caution** Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)**

***5795***

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**Authority required (STREAMLINED)**

***5554***

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL**

| 9500B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *489.02 | CellCept [RO] |

**mycophenolate mofetil 500 mg tablet, 50**

| 9502D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 6 | 5 | .. | *263.76 | [a] APO-Mycophenolate [TX]<br>[a] Ceptolate [AF]<br>[a] Mycophenolate Sandoz [SZ] | [a] CellCept [RO]<br>[a] Mycophenolate AN [EA]<br>[a] Pharmacor Mycophenolate 500 [CR] |

## ▪ MYCOPHENOLATE

**Caution** Careful monitoring of patients is mandatory.

**Note** Management includes initiation, stabilisation and review of therapy as required.

**Authority required (STREAMLINED)**

***4084***

Prophylaxis of renal allograft rejection

Treatment Phase: Management

**Clinical criteria:**

- The treatment must be under the supervision and direction of a transplant unit.

**Authority required (STREAMLINED)**

***4095***

WHO Class III, IV or V lupus nephritis

Treatment Phase: Management

**Clinical criteria:**

- The condition must be proven by biopsy.

**Treatment criteria:**

- Must be treated by a nephrologist or in consultation with a nephrologist.

The name of the consulting nephrologist must be included in the patient medical records.

**mycophenolate 360 mg enteric tablet, 120**

| 9504F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *343.12 | Myfortic [NV] |

**mycophenolate 180 mg enteric tablet, 120**

| 9503E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *171.58 | Myfortic [NV] |

## ▪ MYCOPHENOLATE

**Caution** Careful monitoring of patients is mandatory.

**Note** For item codes 9501C and 1839T, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution

HSD (Public)

**Authority required (STREAMLINED)**

***5653***

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**Authority required (STREAMLINED)**

***5600***

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**mycophenolate mofetil 250 mg capsule, 100**

9501C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 6 | 5 | .. | *263.88 | [a] APO-Mycophenolate [TX]<br>[a] Mycophenolate Sandoz [SZ] | [a] CellCept [RO]<br>[a] Pharmacor Mycophenolate 250 [CR] |

**mycophenolate Capsule 250 mg, 50**

1839T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 12 | 5 | .. | *263.88 | [a] Ceptolate [AF] |

## ▪ NATALIZUMAB

**Caution** Progressive multifocal leukoencephalopathy has been reported with this drug.

**Authority required (STREAMLINED)**

***6875***

Clinically definite relapsing-remitting multiple sclerosis

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support), **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years, **AND**
- The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; OR
- Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient.

**Population criteria:**

- Patient must be aged 18 years or older.

The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.

Treatment with this drug must cease if there is continuing progression of disability whilst the patient is being treated with this drug.

For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug.

Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

**natalizumab 300 mg/15 mL injection, 15 mL vial**

9505G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 5 | .. | 1489.64 | Tysabri [BD] |

## ▪ SIROLIMUS

**Caution** Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)**

***5795***

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**sirolimus 2 mg tablet, 100**

9548M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 5 | .. | *2748.68 | Rapamune [PF] |

HSD (Public)

**sirolimus 1 mg tablet, 100**

| 9549N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1374.32 | Rapamune [PF] |

**sirolimus 1 mg/mL oral liquid, 60 mL**

| 9550P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *889.20 | Rapamune [PF] |

**sirolimus 500 microgram tablet, 100**

| 9747B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *687.18 | Rapamune [PF] |

## ▪ VEDOLIZUMAB

**Note** Special Pricing Arrangements apply.

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of infliximab, vedolizumab and adalimumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either infliximab, vedolizumab or adalimumab at any one time. From 1 December 2016, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial each of PBS-subsidised infliximab, vedolizumab or adalimumab without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with infliximab, vedolizumab or adalimumab while they continue to show a response to therapy. A patient who received PBS-subsidised infliximab, vedolizumab or adalimumab treatment prior to 1 December 2016 is considered to be in their first cycle as of 1 December 2016. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised infliximab, vedolizumab or adalimumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised infliximab, vedolizumab or adalimumab treatment in the most recent cycle to the date of the first application for initial treatment with infliximab, vedolizumab or adalimumab under the new treatment cycle. A patient who has failed fewer than 3 trials of either infliximab, vedolizumab or adalimumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

(1) How to prescribe PBS-subsidised treatment with infliximab, vedolizumab and adalimumab after therapy after 1 December 2016 .

(a) Initial treatment. Applications for initial treatment should be made where:

(i) an adult patient has received no prior PBS-subsidised treatment with infliximab, vedolizumab or adalimumab in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) an adult patient has received prior PBS-subsidised (initial or continuing) infliximab, vedolizumab or adalimumab therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) an adult patient wishes to re-commence treatment with infliximab, vedolizumab or adalimumab following a break in PBS-subsidised therapy with the same agent (Initial 2).

Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab , 14 weeks of therapy for infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab, and this assessment must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is provided to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with infliximab, vedolizumab or adalimumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment. Assessments of response to a course of PBS-subsidised therapy must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate infliximab, vedolizumab or adalimumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy. A patient may trial an alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with infliximab, vedolizumab or adalimumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate infliximab, vedolizumab or adalimumab therapy should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

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(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Mayo clinic score or partial Mayo clinic score submitted with the first authority application for infliximab, vedolizumab or adalimumab. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is provided within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised infliximab, vedolizumab or adalimumab therapy of at least 5 years, must requalify for initial treatment with respect to the scores of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the Mayo score is measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.
A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 December 2016 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

HSD (Public)

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment (new patient – Initial 1)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 1 month old at the time of application.

Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose for patients administered doses at weeks 0, 2 and 6 (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

Patients must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

**Note** Details of accepted toxicities including severity can be found on the Department of Human Services website at www.humanservices.gov.au.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

**Note** No applications for increased repeats will be authorised.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Change or Re-commencement of treatment after a break in therapy (Initial 2)

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for adalimumab, infliximab or vedolizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with vedolizumab for this condition more than once in the current treatment cycle, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Population criteria:**

- Patient must be aged 18 years or older.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses of treatment may be requested by telephone by contacting the Department of Human Services.

**Note** No applications for increased repeats will be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (Change or Recommencement of treatment after a break in therapy) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses (Initial 1 and Initial 2 restrictions) or 2 repeats (Continuing restriction), **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

**vedolizumab 300 mg injection, 1 vial**

10384M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 3105.19 | Entyvio [TK] |

## ▪ VEDOLIZUMAB

**Note** No applications for increased maximum quantities will be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

**Note** **TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).
Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.
From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.
A patient who received PBS-subsidised adalimumab, infliximab,or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.
A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.
From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.
For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
(b) Continuing treatment.
Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human

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Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.
A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.
(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.
A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

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**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment (new patient – initial 1)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, **AND**
- Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR
- Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or

(c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

**Note** This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

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Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe Crohn disease

Treatment Phase: Initial PBS-subsidised treatment (Grandfather)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 August 2015.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with this drug; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

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Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug to complete 24 weeks of treatment under the Initial PBS-subsidised treatment restriction for patients who had previously received non-PBS subsidised treatment (Grandfathered patient), **AND**
- The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing or Grandfathered patients), **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

**Note** Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Severe Crohn disease

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests and diagnostic imaging studies, must be made within 1 month of the date of application.

HSD (Public)

If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

**vedolizumab 300 mg injection, 1 vial**

| 10390W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 3105.19 | Entyvio [TK] |

*Tumor necrosis factor alpha (TNF-) inhibitors*

## ▪ ADALIMUMAB

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have severe active juvenile idiopathic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR
- Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

HSD (Public)

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

HSD (Public)

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with adalimumab for this condition in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

HSD (Public)

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

HSD (Public)

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient adalimumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient adalimumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with adalimumab, **AND**
- Patient must have received adalimumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient adalimumab therapy under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

9663N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 1279.86 | Humira [VE] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

9662M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 1279.86 | Humira [VE] |

**adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

9661L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 1279.86 | Humira [VE] |

## ▪ ETANERCEPT

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have severe active juvenile idiopathic arthritis, **AND**

- Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR
- Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is

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measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with etanercept for this condition in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient etanercept therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient etanercept therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with etanercept, **AND**
- Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
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**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

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A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient etanercept therapy under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

| 5733R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 939.25 | Enbrel [PF] |

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

| 5735W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 939.25 | Enbrel [PF] |

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

| 5734T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 469.63 | Enbrel [PF] |

## ▪ INFLIXIMAB

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***4524***

Acute severe ulcerative colitis

**Treatment criteria:**

- Must be treated by a gastroenterologist; OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology].

**Clinical criteria:**

- Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application, **AND**
- Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; OR
- Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below, **AND**
- Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital.

**Population criteria:**

- Patient must be 6 years of age or older.

For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where:

(i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L

(ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood.

For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours.

At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient's medical records.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

**infliximab 100 mg injection, 1 vial**

| 10067W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 5 | 1 | .. | *2537.10 | [a] Inflectra [PF]<br>[a] Renflexis [MK] | [a] Remicade [JC] |

## ▪ INFLIXIMAB

**Note** Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

HSD (Public)

(3) Baseline measurements to determine response.
Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.
A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 're-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

HSD (Public)

**Authority required**

Initial 1

Initial treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has an externally draining enterocutaneous or rectovaginal fistula; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6 will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

The authority application must be made in writing

**Authority required**

Initial 2

Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and

(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for

adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

The authority application must be made in writing

**Authority required**

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

(a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with infliximab prior to 1 March 2010; and

(b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with infliximab; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) is receiving treatment with infliximab at the time of application; and

(e) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with infliximab.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

HSD (Public)

Patients may qualify for PBS-subsidised treatment under this restriction once only

The authority application must be made in writing

**Authority required**

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

The authority application must be made in writing

**infliximab 100 mg injection, 1 vial**

| 9654D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 507.42 | [a] Inflectra [PF]<br>[a] Renflexis [MK] | [a] Remicade [JC] |

## ▪ INFLIXIMAB

**Note** Special Pricing Arrangements apply.

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time.

For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

HSD (Public)

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2015.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to theDepartment of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.
For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient with severe disease may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).
A patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PCDAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.
Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.
A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with

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adalimumab will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

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**Authority required**

Moderate to severe Crohn disease

Treatment Phase: Initial treatment (new paediatric patient) of Crohn disease in a paediatric patient assessed by PCDAI (Initial 1)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have, at the time of application, disease severity considered to be moderate to severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment and which is no more than 1 month old at the time of application.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription forms; and

(b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition; and

(iii) the signed patient or guardian acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Human Services website (www.humanservices.gov.au).

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs

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**Authority required**

Moderate to severe Crohn disease

Treatment Phase: Change or re-commencement of treatment of Crohn disease in a paediatric patient assessed by PCDAI (Initial 2)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have a documented history of moderate to severe Crohn disease, **AND**
- Patient must in this treatment cycle, have received prior PBS-subsidised treatment with this drug for this condition; OR
- Patient must in this treatment cycle, have received prior PBS-subsidised treatment with adalimumab for this condition, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and

(ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Moderate to severe Crohn disease

Treatment Phase: Continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

**Clinical criteria:**

- Patient must have a documented history of moderate to severe Crohn disease.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**

- Patient must have demonstrated an adequate response to treatment with this drug as defined as a reduction in PCDAI Score by at least 15 points as compared to baseline and a total of PCDAI score of 30 points or less with the PCDAI assessment being no more than 1 month old at the time of application.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:

(i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with this drug, a PCDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the 'Balance of Supply' treatment phase PBS restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Moderate to severe Crohn disease

Treatment Phase: Balance of supply for a paediatric patient

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under Initial 1 (new patient or patient recommencing treatment after break of more than 5 years) or Initial 2 (change or recommencement of treatment after a break of less than 5 years) or Continuing treatment to complete the maximum duration of treatment specified in the relevant treatment phase, **AND**
- The treatment must provide no more than the balance of up to 3 doses or 2 repeats.

**Note** Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats should be forwarded to:
Department of Human Services
Complex Drugs
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**infliximab 100 mg injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5755X | 1 | .. | .. | 507.42 | [a] Inflectra [PF]<br>[a] Renflexis [MK] | [a] Remicade [JC] |

## ▪ INFLIXIMAB

**Note** No applications for increased maximum quantities will be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).
Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.
From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.
A patient who received PBS-subsidised adalimumab, infliximab,or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.
A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.
From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.
For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
(b) Continuing treatment.
Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

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Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.
A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.
(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.
A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment (new patient - initial 1)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR

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- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, **AND**
- Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR
- Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

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- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction.

Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing treatment).

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Population criteria:**

- Patient must be aged 18 years or older.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

**Authority required**

Severe Crohn disease

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**

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- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

Up to a maximum of 2 repeats will be authorised.

**infliximab 100 mg injection, 1 vial**

5754W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 507.42 | [a] Inflectra [PF]<br>[a] Renflexis [MK] | [a] Remicade [JC] |

## ▪ INFLIXIMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of infliximab, vedolizumab and adalimumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either infliximab, vedolizumab or adalimumab at any one time. From 1 December 2016, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial each of PBS-subsidised infliximab, vedolizumab or adalimumab without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with infliximab, vedolizumab or adalimumab while they continue to show a response to therapy. A patient who received PBS-subsidised infliximab, vedolizumab or adalimumab treatment prior to 1 December 2016 is considered to be in their first cycle as of 1 December 2016. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised infliximab, vedolizumab or adalimumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised infliximab, vedolizumab or adalimumab treatment in the most recent cycle to the date of the first application for initial treatment with infliximab, vedolizumab or adalimumab under the new treatment cycle. A patient who has failed fewer than 3 trials of either infliximab, vedolizumab or adalimumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

(1) How to prescribe PBS-subsidised treatment with infliximab, vedolizumab and adalimumab after therapy after 1 December 2016 .

(a) Initial treatment. Applications for initial treatment should be made where:

(i) an adult patient has received no prior PBS-subsidised treatment with infliximab, vedolizumab or adalimumab in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) an adult patient has received prior PBS-subsidised (initial or continuing) infliximab, vedolizumab or adalimumab therapy

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and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) an adult patient wishes to re-commence treatment with infliximab, vedolizumab or adalimumab following a break in PBS-subsidised therapy with the same agent (Initial 2).
Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab , 14 weeks of therapy for infliximab and vedolizumab.
A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab, and this assessment must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is provided to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with infliximab, vedolizumab or adalimumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment. Assessments of response to a course of PBS-subsidised therapy must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate infliximab, vedolizumab or adalimumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy. A patient may trial an alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with infliximab, vedolizumab or adalimumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate infliximab, vedolizumab or adalimumab therapy should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Mayo clinic score or partial Mayo clinic score submitted with the first authority application for infliximab, vedolizumab or adalimumab. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is provided within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised infliximab, vedolizumab or adalimumab therapy of at least 5 years, must requalify for initial treatment with respect to the scores of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the Mayo score is measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.
A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 December 2016 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to infliximab and adalimumab only.A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time. Infliximab and adalimumab are PBS-subsidised for moderate to severe disease while only infliximab is PBS-subsidised for acute severe disease.From 1 June 2017, under the PBS, all will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent.Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 June 2017 is considered to be in their first cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice. Once a patient has either failed or ceased to respond to

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treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 June 2017.(a) Initial treatment.Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient has received prior PBS-subsidised (initial or continuing) treatment with a TNF-alfa antagonist and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping treatment' below]; or (iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2). Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted tothe Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply. Assessments of response to a course of PBS-subsidised treatment must be submitted the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.(2) Swapping treatment. Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.A patient may trial an alternate agent at any time, regardless of whether they are receiving treatment (initial or continuing) with infliximab or adalimumab at the time of the application. However, a patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PUCAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the PUCAI score is measured.(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab. A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 June 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction.A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

**Note** Special Pricing Arrangements apply.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years; OR
- Patient must have previously received induction therapy with this drug for an acute severe episode of ulcerative colitis in the last 4 months and demonstrated an adequate response to induction therapy by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 (if aged 6 to 17 years).

**Population criteria:**

- Patient must be 6 years of age or older.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the signed patient acknowledgement or guardian acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 1 month old at the time of application.

Where treatment for an acute severe episode has occurred, an adequate response to induction therapy needs to be demonstrated by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 (if aged 6 to 17 years), within the first 12 weeks of receiving this drug for acute severe ulcerative colitis.

Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 within the first 12 weeks of receiving this drug for ulcerative colitis, or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or have failed to maintain a PUCAI score less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose for patients administered doses at weeks 0, 2 and 6 (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The patient or guardian (required if patient is aged 6 to 17 years) must have signed a patient acknowledgement indicating that he or she understands and acknowledges that the PBS-subsidised treatment will cease if he or she does not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:

HSD (Public)

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing

**Note** No applications for increased repeats will be authorised.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Change or Re-commencement of treatment after a break in therapy (Initial 2)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with adalimumab, infliximab or vedolizumab for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with adalimumab or infliximab for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have failed PBS-subsidised treatment with infliximab for this condition in the current treatment cycle; OR
- Patient must not have failed PBS-subsidised treatment with infliximab for this condition in the current treatment cycle more than once if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug.

Applications for authorisation of initial treatment must be in writing and must include:(a) a completed authority prescription form; and(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy];

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

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Up to a maximum of 2 repeats will be authorised.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

**Note** No applications for increased repeats will be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (Change or Recommencement of treatment after a break in therapy) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses (Initial 1 and Initial 2 restrictions) or 2 repeats (Continuing restriction).

**Population criteria:**

- Patient must be 6 years of age or older.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

**infliximab 100 mg injection, 1 vial**

10196P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 507.42 | [a] Inflectra [PF]<br>[a] Renflexis [MK] | [a] Remicade [JC] |

## ▪ INFLIXIMAB

**Authority required**

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or secukinumab in this treatment cycle, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

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The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 18 weeks of treatment with this drug will be approved under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be eligible to receive further bDMARD therapy.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 18 weeks of treatment with this drug will be approved under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept,

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golimumab, infliximab and secukinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.
Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised bDMARD therapy
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Grandfather patients - secukinumab only.
For patients who commenced treatment with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction
(c) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

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A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

**Clinical criteria:**

- Patient must have active, or a documented history of active, ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 18 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 18 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 18 weeks treatment available under the above restrictions.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

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Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Grandfather patients - secukinumab only.

For patients who commenced treatment with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction

(c) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised

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baseline measurements.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001



**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**infliximab 100 mg injection, 1 vial**

| 5753T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 507.42 | [a] Inflectra [PF]<br>[a] Renflexis [MK] | [a] Remicade [JC] |

## ▪ INFLIXIMAB

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must have not failed previous PBS-subsidised treatment with infliximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20

mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application including severity.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

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(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
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**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New

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baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**

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- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

If a patient fails to demonstrate a response to a treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for

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treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of

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rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient infliximab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient infliximab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with infliximab, **AND**
- Patient must have received infliximab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats will be authorised.

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

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Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the

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baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient infliximab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**infliximab 100 mg injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5757B | 1 | .. | .. | 507.42 | [a] Inflectra [PF]<br>[a] Renflexis [MK] | [a] Remicade [JC] |

## ▪ INFLIXIMAB

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe active psoriatic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

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(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

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An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

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Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of

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treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.
Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
Grandfather patients - ustekinumab and secukinumab only.
For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

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on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
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**infliximab 100 mg injection, 1 vial**

| 5756Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 507.42 | [a] Inflectra [PF]<br>[a] Renflexis [MK] | [a] Remicade [JC] |

## ▪ INFLIXIMAB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.
Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.
Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.
Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.
Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

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There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Application for approval for initial treatment.
Applications for a course of initial treatment should be made in the following situations:
(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or
(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.
Grandfather patients (ixekizumab only).
Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Application for continuing treatment.
Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.
For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
(4) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.
(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**

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- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

HSD (Public)

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) restriction to complete 22 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

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(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**infliximab 100 mg injection, 1 vial**

5758C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 507.42 | [a] Inflectra [PF]<br>[a] Renflexis [MK] | [a] Remicade [JC] |

*Interleukin inhibitors*

## ▪ ANAKINRA

**Note** This drug is not PBS-subsidised for conditions other than CAPS.

**Authority required (STREAMLINED)**

***5450***

Moderate to severe cryopyrin associated periodic syndromes (CAPS)

**Treatment criteria:**

- Must be treated by a rheumatologist or in consultation with a rheumatologist; OR
- Must be treated by a clinical immunologist or in consultation with a clinical immunologist.

A diagnosis of CAPS must be documented in the patient's medical records.

**anakinra 100 mg/0.67 mL injection, 28 x 0.67 mL syringes**

10264F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 5 | .. | 1650.00 | Kineret [FK] |

## ▪ TOCILIZUMAB

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have severe active juvenile idiopathic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR
- Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

HSD (Public)

HSD (Public)

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than

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12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply.

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with tocilizumab, **AND**
- Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological

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therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment – balance of supply

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**

- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

| 10077J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 102.74 | Actemra [RO] |

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

| 10056G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 254.66 | Actemra [RO] |

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

| 10064Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 506.74 | Actemra [RO] |

## ▪ TOCILIZUMAB

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR
- Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

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There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

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(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

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- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have demonstrated an adequate response to treatment with tocilizumab, **AND**
- Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in

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their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment – balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

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**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

| 10081N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 102.74 | Actemra [RO] |

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

| 10058J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 254.66 | Actemra [RO] |

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

| 10072D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 506.74 | Actemra [RO] |



## ▪ TOCILIZUMAB

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with tocilizumab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs

specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

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(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an

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alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) completed authority prescription form(s); and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to a treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure

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uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services

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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with tocilizumab, **AND**
- Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a

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disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

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A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 9657G | 1 | .. | .. | 102.74 | Actemra [RO] |

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 9658H | 1 | .. | .. | 254.66 | Actemra [RO] |

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 9659J | 1 | .. | .. | 506.74 | Actemra [RO] |

## ▪ TOCILIZUMAB

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a

patient who has severe active systemic juvenile idiopathic arthritis (sJIA).
From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show a response to therapy, and
(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.
Once a patient has either failed or ceased to respond to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to receive further PBS-subsidised tocilizumab therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was stopped to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.
A patient who was receiving PBS-subsidised tocilizumab treatment immediately prior to 1 May 2012 is considered to be in their first cycle as of 1 May 2012. A patient who has had a break in tocilizumab treatment of at least 12 months immediately prior to making a new application, on or after 1 May 2012, will commence a new treatment cycle.
A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of less than 12 months may commence a second course of treatment within the same treatment cycle.
A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
(1) How to prescribe PBS-subsidised tocilizumab therapy after 1 May 2012.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised tocilizumab treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain a response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2); or
(iv) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab for that course.
For second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with tocilizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted tocilizumab supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.
(2) Treatment cycle.
Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count) or the prior therapy requirements, except if the patient has had a break in therapy of more than 12 months.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.
Where a patient is deemed to have failed to respond or to sustain a response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. The Department of Human Services will assess response according to these revised baseline measurements. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used by the Department of Human Services to assess response to the second course.
(4) Recommencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

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**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

**Clinical criteria:**

- Patient must have been diagnosed with systemic juvenile idiopathic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with tocilizumab for this condition; OR
- Patient must not have received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 2 active joints; and

(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or

(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:

(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(ii) details of prior treatment including dose and duration of treatment;

(iii) pathology reports detailing CRP and platelet count where appropriate; and

(3) an acknowledgement signed by a parent or authorised guardian.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to 2 courses of treatment in a treatment cycle they will not be eligible to receive further PBS-subsidised tocilizumab therapy in that treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

**Note** To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be provided for all subsequent continuing treatment applications.

**Note** Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 4 weeks from the date of

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completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)

**Clinical criteria:**

- Patient must have a documented history of systemic juvenile idiopathic arthritis, **AND**
- Patient must have received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months, **AND**
- Patient must not have failed to demonstrate an adequate response to PBS-subsidised therapy with tocilizumab for this condition more than once in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to that course of treatment with tocilizumab.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

**Note** Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:

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Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy under the Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy under the Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of systemic juvenile idiopathic arthritis, **AND**
- Patient must have demonstrated an adequate response to their most recent course of PBS-subsidised treatment with tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the most recent prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

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Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

**Note** An assessment of the patient's response to a continuing course of therapy should be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

| 1476Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 102.74 | Actemra [RO] |

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

| 1481Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 254.66 | Actemra [RO] |

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

| 1482B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 506.74 | Actemra [RO] |

## ▪ USTEKINUMAB

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).
Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.

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From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.
A patient who received PBS-subsidised adalimumab, infliximab,or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.
A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.
From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.
For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
(b) Continuing treatment.
Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab

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(where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.
A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.
(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.
A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment (new patient - initial 1)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug, **AND**
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, **AND**
- Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR
- Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric

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lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

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**Authority required**

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4

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vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

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**ustekinumab 130 mg/26 mL injection, 26 mL vial**

| 11182M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 4 | .. | .. | *16929.24 | Stelara [JC] |

*Calcineurin inhibitors*

## ▪ CYCLOSPORIN

**Caution** Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)**

***6628***

Management of transplant rejection

**Clinical criteria:**

- The treatment must be used by organ or tissue transplant recipients.

**cyclosporin 50 mg/mL injection, 10 x 1 mL ampoules**

| 5631J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 54.10 | Sandimmun [NV] |

## ▪ CYCLOSPORIN

**Caution** Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)**

***6643***

Management of transplant rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must have had an organ or tissue transplantation, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**Authority required (STREAMLINED)**

***6660***

Severe atopic dermatitis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Treatment criteria:**

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologists.

**Clinical criteria:**

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies.

**Authority required (STREAMLINED)**

***6676***

Severe psoriasis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies, **AND**
- The condition must have caused significant interference with quality of life.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Authority required (STREAMLINED)**

***6631***

Nephrotic syndrome

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must have failed prior treatment with steroids and cytostatic drugs; OR
- Patient must be intolerant to treatment with steroids and cytostatic drugs; OR
- The condition must be considered inappropriate for treatment with steroids and cytostatic drugs, **AND**
- Patient must not have renal impairment.

**Treatment criteria:**

- Must be treated by a nephrologist.

**Authority required (STREAMLINED)**

***6638***

Severe active rheumatoid arthritis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- The condition must have been ineffective to prior treatment with classical slow-acting anti-rheumatic agents (including methotrexate); OR
- The condition must be considered inappropriate for treatment with slow-acting anti-rheumatic agents (including methotrexate).

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist.

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**cyclosporin 100 mg/mL oral liquid, 50 mL**

| 5633L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 4 | 5 | .. | *1263.16 | Neoral [NV] |

**cyclosporin 10 mg capsule, 60**

| 5632K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *74.40 | Neoral 10 [NV] |

**cyclosporin 50 mg capsule, 30**

| 5635N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | 5 | .. | *268.16 | [a] Cyclosporin Sandoz [SZ] | [a] Neoral 50 [NV] |

**cyclosporin 25 mg capsule, 30**

| 5634M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | 5 | .. | *128.88 | [a] Cyclosporin Sandoz [SZ] | [a] Neoral 25 [NV] |

**cyclosporin 100 mg capsule, 30**

| 5636P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | 5 | .. | *546.40 | [a] Cyclosporin Sandoz [SZ] | [a] Neoral 100 [NV] |

## ▪ TACROLIMUS

**Caution** Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)**

***5569***

Management of rejection in patients following organ or tissue transplantation

**Clinical criteria:**

- The treatment must be under the supervision and direction of a transplant unit, **AND**
- The treatment must include initiation, stabilisation, and review of therapy as required.

**tacrolimus 1 mg modified release capsule, 60**

| 9665Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *263.28 | [a] ADVAGRAF XL [LQ] | [a] Prograf XL [LL] |

**tacrolimus 2 mg capsule, 100**

| 10860N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *1000.00 | Tacrolimus Sandoz [SZ] |

**tacrolimus 1 mg capsule, 100**

| 9560E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *438.80 | [a] Pacrolim [AF]<br>[a] Prograf [LL] | [a] Pharmacor Tacrolimus 1 [CR]<br>[a] TACROLIMUS APOTEX [TX] |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | [a] Tacrolimus Sandoz [SZ] | |

**tacrolimus 5 mg modified release capsule, 30**

| 9666R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *750.44 | [a] ADVAGRAF XL [LQ] | [a] Prograf XL [LL] |

**tacrolimus 5 mg capsule, 50**

| 9561F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1096.44 | [a] Pacrolim [AF]<br>[a] Prograf [LL]<br>[a] Tacrolimus Sandoz [SZ] | [a] Pharmacor Tacrolimus 5 [CR]<br>[a] TACROLIMUS APOTEX [TX] |

**tacrolimus 500 microgram modified release capsule, 30**

| 9664P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *75.04 | [a] ADVAGRAF XL [LQ] | [a] Prograf XL [LL] |

**tacrolimus 750 microgram capsule, 100**

| 10859M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *375.00 | Tacrolimus Sandoz [SZ] |

**tacrolimus 500 microgram capsule, 100**

| 9558C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *219.40 | [a] Pacrolim [AF]<br>[a] Prograf [LL]<br>[a] Tacrolimus Sandoz [SZ] | [a] Pharmacor Tacrolimus 0.5 [CR]<br>[a] TACROLIMUS APOTEX [TX] |

*Other immunosuppressants*

## ▪ LENALIDOMIDE

**Note** Special Pricing Arrangements apply.

**Authority required**

Myelodysplastic syndrome

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be limited to a maximum duration of 16 weeks, **AND**
- Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), **AND**
- Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, **AND**
- Patient must be red blood cell transfusion dependent.

Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination: less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias.

Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations:

1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR
2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR
5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias.

Classification of a patient as red blood cell transfusion dependent requires that:

(i) the patient has been transfused within the last 8 weeks; and

(ii) the patient has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and would be expected to continue this requirement without lenalidomide treatment.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Myelodysplastic Syndrome Lenalidomide Authority Application - Supporting Information Form; and

(c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and

(d) a copy of the full blood examination report; and

(e) a copy of the pathology report detailing the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note: using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS -5q is acceptable); and

(f) details of transfusion requirements including: (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red cell units transfused in the 4 and 6 months preceding the date of this application; and

(g) a signed patient acknowledgement form.

HSD (Public)

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), **AND**
- Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, **AND**
- Patient must have received PBS-subsidised initial therapy with lenalidomide for myelodysplastic syndrome, **AND**
- Patient must have achieved and maintained transfusion independence; or least a 50% reduction in red blood cell unit transfusion requirements compared with the four month period prior to commencing initial PBS-subsidised therapy with lenalidomide, **AND**
- Patient must not have progressive disease.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

The first authority application for continuing supply must be made in writing. Subsequent authority applications for continuing supply may be made by telephone.

The following evidence of response must be provided at each application:

(i) a haemoglobin level taken within the last 4 weeks; and

(ii) the date of the last transfusion; and

(iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application; and

(iv) a statement confirming that the patient has not progressed to acute myeloid leukaemia.

**Note** Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Subsequent authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**lenalidomide 5 mg capsule, 21**

2799H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 3 | .. | 5122.76 | Revlimid [CJ] |

**lenalidomide 10 mg capsule, 21**

2802L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 3 | .. | 5361.16 | Revlimid [CJ] |

## ▪ LENALIDOMIDE

**Note** Special Pricing Arrangements apply.

**Authority required**

Multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

**Clinical criteria:**

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

HSD (Public)

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Thalidomide treatment failure is defined as:

(1) confirmed disease progression during thalidomide treatment or within 6 months of discontinuing thalidomide treatment; or

(2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment.

Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living.

Toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity.

Failure to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease is defined as:

(1) less than a 25% reduction in serum or urine M protein; or

(2) in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum free light chain levels.

If the dosing requirement for thalidomide cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and

(3) duration of thalidomide and daily dose prescribed; and

(4) a signed patient acknowledgment.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

**Clinical criteria:**

- Patient must have previously received an authority prescription for lenalidomide, **AND**
- Patient must not have progressive disease, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with dexamethasone.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

HSD (Public)

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001



**lenalidomide 15 mg capsule, 21**

5785L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 6252.53 | Revlimid [CJ] |

**lenalidomide 5 mg capsule, 21**

5783J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 5122.76 | Revlimid [CJ] |

**lenalidomide 25 mg capsule, 21**

5786M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 6587.49 | Revlimid [CJ] |

**lenalidomide 10 mg capsule, 21**

5784K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 5361.16 | Revlimid [CJ] |

## ▪ LENALIDOMIDE

**Caution** This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

**Note** Special Pricing Arrangements apply.

**Authority required**

Multiple myeloma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be ineligible for a primary stem cell transplantation, **AND**
- Patient must not be receiving PBS subsidised bortezomib for this condition, **AND**
- The treatment must be in combination with dexamethasone.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, and ineligibility for prior stem cell transplant; and nomination of which disease activity parameters will be used to assess response; and

(3) a signed patient acknowledgement.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should

be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Patient must be registered in the i-access risk management program.

**Authority required**

Multiple myeloma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been authorised with a PBS prescription with this drug for the condition, **AND**
- Patient must not have demonstrated progressive disease, **AND**
- Patient must not be receiving PBS subsidised bortezomib for this condition, **AND**
- The treatment must be in combination with dexamethasone.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**lenalidomide 15 mg capsule, 21**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 11062F | 1 | .. | .. | 6252.53 | Revlimid [CJ] |

**lenalidomide 5 mg capsule, 21**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 11029L | 1 | .. | .. | 5122.76 | Revlimid [CJ] |

**lenalidomide 25 mg capsule, 21**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 11041D | 1 | .. | .. | 6587.49 | Revlimid [CJ] |

**lenalidomide 10 mg capsule, 21**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 11064H | 1 | .. | .. | 5361.16 | Revlimid [CJ] |

## ▪ POMALIDOMIDE

**Caution** This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

**Note** Special Pricing Arrangements apply.

**Authority required**

Multiple myeloma

Treatment Phase: Initial treatment

HSD (Public)

**Clinical criteria:**

- The treatment must be in combination with dexamethasone, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must have experienced treatment failure with lenalidomide, **AND**
- Patient must have experienced treatment failure with bortezomib, **AND**
- Patient must not be receiving concomitant PBS-subsidised thalidomide, lenalidomide or bortezomib.

Bortezomib treatment failure is the absence of achieving at least a partial response or as progressive disease during treatment or within 6 months of discontinuing treatment with bortezomib. Lenalidomide treatment failure is progressive disease during treatment or within 6 months of discontinuing treatment with lenalidomide.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma pomalidomide Authority Application Supporting Information form; and

(3) reports demonstrating the patient has failed treatment with lenalidomide and bortezomib.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Multiple myeloma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have progressive disease, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must not be receiving concomitant PBS-subsidised thalidomide, lenalidomide or bortezomib.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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HSD (Public)

**pomalidomide 4 mg capsule, 21**

| 10387Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 10500.00 | Pomalyst [CJ] |

**pomalidomide 3 mg capsule, 21**

| 10406Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 10500.00 | Pomalyst [CJ] |

## ▪ RITUXIMAB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

HSD (Public)

Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with rituximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 2 infusions of rituximab under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'TNF' alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made at least 12 weeks after the first infusion so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services within 4 weeks of the date it was conducted. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient who fails to demonstrate a response to treatment with rituximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who fails to demonstrate a response to rituximab treatment and who qualifies to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

HSD (Public)

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 2 infusions of rituximab under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'TNF' alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) completed authority prescription form(s); and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with rituximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised rituximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised rituximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response at least 12 weeks after the first infusion. This assessment must be submitted no later than 4 weeks from the date of the assessment.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient fails to demonstrate a response to a treatment with rituximab and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

HSD (Public)

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as the most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition, **AND**
- Patient must not receive more than 2 infusions of rituximab under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) completed authority prescription form(s); and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**rituximab 500 mg/50 mL injection, 50 mL vial**

| 9544H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 1864.22 | Mabthera [RO] |

## ▪ THALIDOMIDE

**Caution** Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

**Note** Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program.

**Authority required (STREAMLINED)**

***5914***

Multiple myeloma

**thalidomide 100 mg capsule, 28**

| 9667T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | .. | .. | *1596.00 | Thalomid [CJ] |

**thalidomide 50 mg capsule, 28**

| 9566L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 4 | .. | .. | *1596.00 | Thalomid [CJ] |

# ▪ MUSCULO-SKELETAL SYSTEM

## ▪ MUSCLE RELAXANTS

### MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

*Other centrally acting agents*

## ▪ BACLOFEN

**Note** Pharmaceutical benefits that have the form baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule and pharmaceutical benefits that have the form baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

***6925***
Severe chronic spasticity
**Clinical criteria:**
- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity of cerebral origin.

**Authority required (STREAMLINED)**
***6939***
Severe chronic spasticity
**Clinical criteria:**
- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to multiple sclerosis.

**Authority required (STREAMLINED)**
***6940***
Severe chronic spasticity
**Clinical criteria:**
- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord injury.

**Authority required (STREAMLINED)**
***6911***
Severe chronic spasticity
**Clinical criteria:**
- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord disease.

**baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule**

5617P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10 | .. | .. | *1246.30 | [a] Bacthecal [DZ] | [a] Lioresal Intrathecal [NV] |

**baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules**

11126N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 1246.30 | [a] Sintetica Baclofen Intrathecal [BZ] |

# DRUGS FOR TREATMENT OF BONE DISEASES

## DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

*Bisphosphonates*

### IBANDRONATE

**Authority required (STREAMLINED)**
***5291***
Bone metastases
**Clinical criteria:**
- The condition must be due to breast cancer.

**ibandronate 6 mg/6 mL injection, 6 mL vial**

5750P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 11 | .. | 324.29 | Bondronat [RO] |

### PAMIDRONATE DISODIUM

**Authority required (STREAMLINED)**
***4433***
Hypercalcaemia of malignancy
**Clinical criteria:**
- Patient must have a malignancy refractory to anti-neoplastic therapy.

**pamidronate disodium 60 mg/10 mL injection, 10 mL vial**

5669J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 2 | .. | 55.26 | Pamisol [PF] |

**pamidronate disodium 15 mg/5 mL injection, 5 mL vial**

5667G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 4 | 2 | .. | *55.24 | Pamisol [PF] |

HSD (Public)

**pamidronate disodium 30 mg/10 mL injection, 10 mL vial**

5668H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 2 | .. | *55.26 | Pamisol [PF] |

## ▪ PAMIDRONATE DISODIUM

**Authority required (STREAMLINED)**

***4433***

Hypercalcaemia of malignancy

**Clinical criteria:**

- Patient must have a malignancy refractory to anti-neoplastic therapy.

**Authority required (STREAMLINED)**

***5218***

Multiple myeloma

**Authority required (STREAMLINED)**

***5291***

Bone metastases

**Clinical criteria:**

- The condition must be due to breast cancer.

**pamidronate disodium 90 mg/10 mL injection, 10 mL vial**

5670K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 11 | .. | 82.89 | Pamisol [PF] |

## ▪ ZOLEDRONIC ACID

**Note** Pharmaceutical benefits that have the form zoledronic acid 4 mg/100 mL injection and pharmaceutical benefits that have the form zoledronic acid 4 mg/5 mL injection are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

***5735***

Multiple myeloma

**Authority required (STREAMLINED)**

***5605***

Bone metastases

**Clinical criteria:**

- The condition must be due to breast cancer.

**Authority required (STREAMLINED)**

***5703***

Bone metastases

**Clinical criteria:**

- The condition must be due to castration-resistant prostate cancer.

**Authority required (STREAMLINED)**

***5704***

Hypercalcaemia of malignancy

**Clinical criteria:**

- Patient must have a malignancy refractory to anti-neoplastic therapy.

**zoledronic acid 4 mg/100 mL injection, 100 mL bag**

10561W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 11 | .. | 245.33 | [a] DBL Zoledronic Acid [PF] |

**zoledronic acid 4 mg/5 mL injection, 5 mL vial**

9653C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 11 | .. | 245.33 | [a] APO-Zoledronic Acid [TX]<br>[a] Zometa [NV] | [a] DBL Zoledronic Acid [PF] |

**zoledronic acid 4 mg/100 mL injection, 100 mL vial**

10548E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 11 | .. | 245.33 | [a] Zometa [NV] |

# ▪ NERVOUS SYSTEM

## ▪ ANTI-PARKINSON DRUGS

### DOPAMINERGIC AGENTS

*Dopa and dopa derivatives*

## ▪ LEVODOPA + CARBIDOPA ANHYDROUS

**Note** Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

HSD (Public)

**Authority required (STREAMLINED)**

***6863***

Advanced Parkinson disease

**Clinical criteria:**

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- The treatment must be commenced in a hospital-based movement disorder clinic.

**levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 9743T | 8 | 5 | .. | *11536.00 | Duodopa [VE] |

*Dopamine agonists*

## ▪ APOMORPHINE

**Authority required (STREAMLINED)**

***6813***

Parkinson disease

**Clinical criteria:**

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.

**apomorphine hydrochloride 100 mg/20 mL injection, 5 x 20 mL vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 11093W | 18 | 5 | .. | *7552.80 | Apomine Solution for Infusion [PF] |

## ▪ APOMORPHINE

**Authority required (STREAMLINED)**

***4833***

Parkinson disease

**Clinical criteria:**

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.

**apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5609F | 72 | 5 | .. | *6528.96 | Movapo [TD] |

**apomorphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10227G | 72 | 5 | .. | *3021.12 | Apomine [PF] |

**apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5610G | 36 | 5 | .. | *8168.04 | Movapo [TD] |

**apomorphine hydrochloride 50 mg/10 mL injection, 5 x 10 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10950H | 36 | 5 | .. | *8168.04 | Movapo PFS [TD] |

# ▪ PSYCHOLEPTICS

## ANTIPSYCHOTICS

*Diazepines, oxazepines, thiazepines and oxepines*

## ▪ CLOZAPINE

**Note** Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Novartis Clozaril Patient Monitoring System (eCPMS) or Hospira Clopineconnect.

**Authority required (STREAMLINED)**

***5015***

Schizophrenia

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient.

**Clinical criteria:**

- Patient must be non-responsive to other neuroleptic agents; OR
- Patient must be intolerant of other neuroleptic agents.

Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.

HSD (Public)

The name of the consulting psychiatrist should be included in the patient's medical records.
A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

**clozapine 200 mg tablet, 100**

| 5627E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | .. | .. | *484.76 | Clopine 200 [PF] |

**clozapine 25 mg tablet, 100**

| 5628F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *64.64 | [a] Clopine 25 [PF] | [a] Clozaril 25 [NV] |

**clozapine 50 mg tablet, 100**

| 5626D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | .. | .. | *129.28 | Clopine 50 [PF] |

**clozapine 100 mg tablet, 100**

| 5629G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *242.38 | [a] Clopine 100 [PF] | [a] Clozaril 100 [NV] |

**clozapine 50 mg/mL oral liquid, 100 mL**

| 5630H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 135.00 | Clopine Suspension [PF] |

HSD (Public)

# RESPIRATORY SYSTEM

## DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

### OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

*Other systemic drugs for obstructive airway diseases*

### MEPOLIZUMAB

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 26 to 30 week assessment, to ensure continuity of treatment for those patients who meet the continuation criteria for PBS-subsidised mepolizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE EOSINOPHILIC ASTHMA**
Patients are eligible to commence a 'mepolizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.
Once a patient has either failed to achieve or maintain a response to mepolizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised mepolizumab therapy before they are eligible to commence the next mepolizumab treatment cycle, or if eligible, an 'omalizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised mepolizumab is stopped to the date of the first application for initial treatment with mepolizumab under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised mepolizumab therapy:
(a) Initial treatment:
Applications for initial treatment should be made where:
i) A patient has received no prior PBS-subsidised mepolizumab treatment and wishes to commence such therapy; or
ii) A patient wishes to recommence treatment with mepolizumab following a break in PBS-subsidised therapy of more than 6 months; or
iii) A patient has received prior PBS-subsidised omalizumab and wishes to commence treatment with mepolizumab after a treatment break of 6 months.
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 32 weeks of therapy for mepolizumab.
(b) Grandfather patients:
For patients who commenced treatment with mepolizumab for uncontrolled severe eosinophilic asthma prior to 1 January 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A

maximum of 24 weeks of treatment with mepolizumab will be authorised under this criterion. Approval will be based on the criteria included in the relevant restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with mepolizumab will be assessed under the continuing treatment restriction.
'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.
(c) Continuing treatment:
Following the completion of the initial treatment course with mepolizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with mepolizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing mepolizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.
(2) Baseline measurements to determine response:
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for mepolizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:
A patient who wishes to trial a second or subsequent mepolizumab treatment cycle, or an initial omalizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Uncontrolled severe eosinophilic asthma

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**

- Patient must be under the care of the same physician for at least 12 months, **AND**
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 1 or more occasions in the previous 12 months, **AND**
- Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 6 weeks, **AND**
- Patient must have signed a patient or parent/guardian acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised omalizumab.

**Population criteria:**

- Patient must be aged 12 years or older.

Optimised asthma therapy includes:

(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; AND

(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

HSD (Public)

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient must be made at time of application for treatment (to establish baseline score) and again around 26 to 30 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment at around 26 to 30 weeks, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with mepolizumab.

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with mepolizumab or omalizumab within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request 7 repeats to provide for an initial course of mepolizumab sufficient for 32 weeks of therapy.

Mepolizumab and omalizumab may not be used concurrently or within 6 months of each other. A patient is required to have ceased treatment with omalizumab for 6 months prior to initiating treatment with mepolizumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Eosinophilic Asthma Initial PBS Authority Application - Supporting Information Form,

which includes the following:

(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and

(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(iii) the signed patient or parent/guardian acknowledgement; and

(c) a copy of the eosinophil pathology report; and

(d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

**mepolizumab 100 mg injection, 1 vial**

10996R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 7 | .. | 1638.00 | Nucala [GK] |

## ▪ MEPOLIZUMAB

**Note** For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

**Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE EOSINOPHILIC ASTHMA**

Patients are eligible to commence a 'mepolizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to mepolizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised mepolizumab therapy before they are eligible to commence the next mepolizumab treatment cycle, or if eligible, an 'omalizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised mepolizumab is stopped to the date of the first application for initial treatment with mepolizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised mepolizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where:

i) A patient has received no prior PBS-subsidised mepolizumab treatment and wishes to commence such therapy; or

ii) A patient wishes to recommence treatment with mepolizumab following a break in PBS-subsidised therapy of more than 6 months; or

iii) A patient has received prior PBS-subsidised omalizumab and wishes to commence treatment with mepolizumab after a treatment break of 6 months.

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 32 weeks of therapy for mepolizumab.

(b) Grandfather patients:

For patients who commenced treatment with mepolizumab for uncontrolled severe eosinophilic asthma prior to 1 January 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with mepolizumab will be authorised under this criterion. Approval will be based on the criteria included in the relevant restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with mepolizumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.

(c) Continuing treatment:

Following the completion of the initial treatment course with mepolizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with mepolizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing mepolizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

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The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for mepolizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent mepolizumab treatment cycle, or an initial omalizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Uncontrolled severe eosinophilic asthma

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**

- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised omalizumab.

**Population criteria:**

- Patient must be aged 12 years or older.

An adequate response to mepolizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline,

OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

All applications for continuing treatment with mepolizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 26 to 30weeks after the first dose of PBS-subsidised mepolizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with mepolizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with mepolizumab.

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with mepolizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of mepolizumab sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Eosinophilic Asthma Continuing PBS Authority Application - Supporting Information Form which includes details of maintenance oral corticosteroid dose; and

(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms

**Note** If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

**Note** It is recommended that second and subsequent applications for continuing treatment are submitted at the time of an 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criteria for PBS-subsidised mepolizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Uncontrolled severe eosinophilic asthma

Treatment Phase: Initial treatment - grandfather patients

**Clinical criteria:**

- Patient must have received non-PBS treatment with this drug for this condition prior to 1 January 2017, **AND**

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- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have had, prior to commencement of mepolizumab, a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) Forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or(ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or(iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, **AND**
- Patient must have had blood eosinophil count greater than or equal to 300 cells per microlitre prior to commencement of mepolizumab, **AND**
- Patient must have had a duration of asthma of at least 1 year prior to commencement of mepolizumab, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy prior to mepolizumab therapy despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must have signed a patient or parent/guardian acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, **AND**
- Patient must have demonstrated an adequate response to treatment with mepolizumab, **AND**
- The treatment must not be used in combination with omalizumab.

**Population criteria:**

- Patient must be aged 12 years or older.

**Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Optimised asthma therapy includes:

(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; AND

(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

A review of the patient's records should be conducted to extract pre- and post-mepolizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations. Parameters to establish response are: (i) a reduction in Asthma Control Questionnaire (ACQ-5) score of at least 0.5; and/or(ii) maintenance oral corticosteroid dose reduced by at least 25% from baseline.

The assessment of the patient's response to the initial PBS subsidised course of treatment must be made at around 18 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The same parameters used to establish response to non-PBS-subsidised therapy with mepolizumab should be used for the assessment.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with mepolizumab.

Patients will be eligible to receive continuing courses of mepolizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with mepolizumab or omalizumab within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of mepolizumab sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Eosinophilic Asthma Grandfather PBS Authority Application - Supporting Information Form, which includes the following:

(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and

(ii) details of pre- and post-mepolizumab data on symptoms, quality of life, medication doses, severe exacerbation/s and hospitalisations, and

(iii) the signed patient or parent/guardian acknowledgement; and

(c) a copy of the pre-mepolizumab eosinophil pathology report.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS subsidised mepolizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**mepolizumab 100 mg injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10980X | 1 | 5 | .. | 1638.00 | Nucala [GK] |

## ▪ OMALIZUMAB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic spontaneous urticaria

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

**Clinical criteria:**

- The condition must be based on both physical examination and patient history (to exclude any factors that may be triggering the urticaria), **AND**
- Patient must have experienced itch and hives that persist on a daily basis for at least 6 weeks despite treatment with H1 antihistamines, **AND**
- Patient must have failed to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy, **AND**
- Patient must not receive more than 12 weeks of treatment under this restriction.

A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following:

1) a H2 receptor antagonist (150 mg twice per day); or

2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or

3) doxepin (up to 25 mg three times a day)

If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.

A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Chronic Spontaneous Urticaria Omalizumab Initial PBS Authority Application - Supporting Information Form which must include:

(i) demonstration of failure to achieve an adequate response to standard therapy; and

(ii) drug names and doses of standard therapies that the patient has failed; and

(iii) a signed patient acknowledgment that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

**omalizumab 150 mg/mL injection, 1 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 11176F | 2 | 2 | .. | *820.00 | Xolair [NV] |

## ▪ OMALIZUMAB

**Authority required**

Severe chronic spontaneous urticaria

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

**Clinical criteria:**

- Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks per authorised course of treatment under this restriction.

**Note** A proportion of patients respond to 150 mg 4-weekly so where a substantial improvement has been obtained with a 300 mg dose it is reasonable to back-titrate dose after initial treatment.

**Note** Cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Severe chronic spontaneous urticaria

Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 September 2017, **AND**
- Patient must have documented history of itch and hives that persisted on a daily basis for at least 6 weeks despite treatment with H1 antihistamines prior to commencing non-PBS subsidised treatment with this drug for this condition, **AND**
- Patient must have documented history of failure to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy prior to commencing non-PBS subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following:

1) a H2 receptor antagonist (150 mg twice per day); or

2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or

3) doxepin (up to 25 mg three times a day)

If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.

A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Chronic Spontaneous Urticaria Omalizumab Initial Grandfather PBS Authority Application - Supporting Information Form which must include:

(i) demonstration of failure to achieve an adequate response to standard therapy; and

(ii) drug names and doses of standard therapies that the patient has failed; and

(iii) a signed patient acknowledgment that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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HSD (Public)

**omalizumab 150 mg/mL injection, 1 mL syringe**

11168T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 5 | .. | *820.00 | Xolair [NV] |

## ▪ OMALIZUMAB

**Note** Special Pricing Arrangements apply.

**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a diagnosis of asthma confirmed and documented by a paediatric respiratory physician, clinical immunologist, or allergist; or paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by the following standard clinical features: forced expiratory volume (FEV1) reversibility or airway hyperresponsiveness or peak expiratory flow (PEF) variability, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE, **AND**
- Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to less than 12 years.

**Treatment criteria:**

- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

**Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months.

Optimised asthma therapy includes:

(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative; AND

(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The initial IgE assessment must be no more than 12 months old at the time of application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used), AND

(b) while receiving optimised asthma therapy in the previous 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) or ACQ-IA assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose, and the assessment of exacerbation rate must be made at around 22 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Paediatric Severe Allergic Asthma Initial PBS Authority Application - Supporting Information form, which includes the following:

(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(iii) acknowledgement signed by a parent or authorised guardian; and

HSD (Public)

(c) a copy of the IgE pathology report; and

(d) a completed Asthma Control Questionnaire (ACQ-5) or the Asthma Control Questionnaire interviewer administered version (ACQ-IA) calculation sheet including the date of assessment of the patient's symptoms and is endorsed with the prescriber's signature.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 22 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**
Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.
Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised omalizumab therapy.
(a) Initial treatment:
Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.
All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.
(b) Grandfather patients:
Paediatric patients who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 December 2016 and who continue to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with omalizumab will be authorised under this restriction. Approval will be based on the criteria included in the grandfather restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.
'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.
(c) Continuing treatment:
Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.
(2) Baseline measurements to determine response:
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and The Department of Human Services will assess response according to these revised baseline measurements.
(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.
(4) Monitoring of patients:
Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Authority required**

HSD (Public)

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of severe allergic asthma, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or ACQ-IA score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 or ACQ-IA score from baseline, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate must be made at around 18 to 22 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Paediatric Severe Allergic Asthma Continuing PBS Authority Application - Supporting Information form which includes details of maintenance oral corticosteroid dose; and

(c) a completed Asthma Control Questionnaire (ACQ-5) or the Asthma Control Questionnaire interviewer administered version (ACQ-IA) calculation sheet including the date of assessment of the patient's symptoms and is endorsed with the signature of the prescriber.

**Note** If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

**Note** For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**
Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.
Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised omalizumab therapy.
(a) Initial treatment:
Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.
All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.
(b) Grandfather patients:
Paediatric patients who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 December 2016 and who continue to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24

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weeks of treatment with omalizumab will be authorised under this restriction. Approval will be based on the criteria included in the grandfather restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.
'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.
(c) Continuing treatment:
Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.
(2) Baseline measurements to determine response:
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and The Department of Human Services will assess response according to these revised baseline measurements.
(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.
(4) Monitoring of patients:
Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

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**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Initial and continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction or Grandfather treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the Initial restriction or up to 24 weeks treatment available under the Continuing or Grandfather restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment under the initial restriction or 24 weeks of treatment under the continuing or grandfather restrictions may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - Grandfather patients

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2016, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have had, prior to commencement of omalizumab, a diagnosis of asthma confirmed and documented by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician, defined by the following standard clinical features: forced expiratory volume (FEV1) reversibility or airway hyperresponsiveness or peak expiratory flow (PEF) variability, **AND**
- Patient must have had a duration of asthma of at least 1 year prior to commencement of omalizumab, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE, **AND**

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- Patient must have failed to achieve adequate control with optimised asthma therapy prior to omalizumab therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must have demonstrated an adequate response to treatment.

**Population criteria:**

- Patient must be aged 6 to less than 12 years.

**Treatment criteria:**

- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

**Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months.

Optimised asthma therapy includes:

(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative; AND

(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

A review of the patient's records should be conducted to extract pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations. Examples of parameters to establish response include:

(i) a reduction in Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire Interviewer Administered (ACQ-IA) score of at least 0.5;

(ii) maintenance oral corticosteroid dose reduced by at least 25% from baseline; and/or

(iii) a reduction in the number of hospitalisations or severe exacerbations requiring use of systemic corticosteroids, compared to the 12 months prior to commencement of omalizumab.

The assessment of the patient's response to the initial PBS subsidised course of treatment must be made at around 18 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The same parameters used to establish response to non-PBS-subsidised therapy with omalizumab should be used for the assessment.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

Patients will be eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

Patients may qualify for PBS-subsidised treatment under this restriction once only.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for an initial course of omalizumab of up to 24 weeks, consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Paediatric Grandfather Severe Allergic Asthma PBS Authority Application - Supporting Information Form, which includes the following:

(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(ii) details of pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations; and

(iii) acknowledgement signed by a parent or authorised guardian.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

HSD (Public)

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.

(b) Grandfather patients:

Paediatric patients who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 December 2016 and who continue to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with omalizumab will be authorised under this restriction. Approval will be based on the criteria included in the grandfather restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.

(c) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and The Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**omalizumab 150 mg/mL injection, 1 mL syringe**

10973M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 410.00 | Xolair [NV] |

**omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe**

10967F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | .. | .. | 205.00 | Xolair [NV] |

## ▪ OMALIZUMAB

**Note** Special Pricing Arrangements apply.

**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**

- Patient must be under the care of the same physician for at least 12 months, **AND**

HSD (Public)

- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 1 or more occasions in the previous 12 months, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or RAST, **AND**
- Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL, **AND**
- Patient must have signed a patient or parent/guardian acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised mepolizumab.

**Population criteria:**

- Patient must be aged 12 years or older.

Optimised asthma therapy includes:

(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; AND

(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The initial IgE assessment must be no more than 12 months old at the time of application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 22 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab or mepolizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form,

which includes the following:

(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and

(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(iii) the signed patient or parent/guardian acknowledgement; and

(c) the IgE pathology report; and

(d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 22 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

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**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** **TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**
Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.
Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next omalizumab treatment cycle or, if eligible, a 'mepolizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab or mepolizumab treatment is stopped to the date of the first application for initial treatment with omalizumab or mepolizumab under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised omalizumab therapy:
(a) Initial treatment:
Applications for initial treatment should be made where:
i) A patient has received no prior PBS-subsidised omalizumab treatment and wishes to commence such therapy; or
ii) A patient wishes to recommence treatment with omalizumab following a break in PBS-subsidised therapy of at least 6 months; or
iii) A patient has received prior PBS-subsidised mepolizumab and wishes to commence treatment with omalizumab after a treatment break of at least 6 months.
All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy of omalizumab.
(b) Continuing treatment:
Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.
(2) Baseline measurements to determine response:
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for omalizumab. For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:
A patient who wishes to trial a second or subsequent omalizumab treatment cycle, or an initial mepolizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.
(4) Monitoring of patients:
Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

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**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - balance of supply

**Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment should be forwarded to:
Department of Human Services

HSD (Public)

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of severe allergic asthma, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised mepolizumab.

**Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Population criteria:**

- Patient must be aged 12 years or older.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction).

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, the assessment of oral corticosteroid dose, and the assessment of time adjusted exacerbation rate must be made at around 18 to 22 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Allergic Asthma PBS Authority Application and Supporting Information Form which includes details of maintenance oral corticosteroid dose; and

(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms and is endorsed with the signature of the prescriber; for patients transitioned from the paediatric to the adolescent/adult restrictions an exacerbation calculation sheet may be submitted.

**Note** If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

**Note** For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

**Note** It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**
Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.
Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next omalizumab treatment cycle or, if eligible, a 'mepolizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab or mepolizumab treatment is stopped to the date of the first application for initial treatment with omalizumab or mepolizumab under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

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(1) How to prescribe PBS-subsidised omalizumab therapy:
(a) Initial treatment:
Applications for initial treatment should be made where:
i) A patient has received no prior PBS-subsidised omalizumab treatment and wishes to commence such therapy; or
ii) A patient wishes to recommence treatment with omalizumab following a break in PBS-subsidised therapy of at least 6 months; or
iii) A patient has received prior PBS-subsidised mepolizumab and wishes to commence treatment with omalizumab after a treatment break of at least 6 months.
All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy of omalizumab.
(b) Continuing treatment:
Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.
(2) Baseline measurements to determine response:
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for omalizumab. For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:
A patient who wishes to trial a second or subsequent omalizumab treatment cycle, or an initial mepolizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.
(4) Monitoring of patients:
Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**omalizumab 150 mg/mL injection, 1 mL syringe**

| 10109C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 410.00 | Xolair [NV] |

**omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe**

| 10118M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | .. | .. | 205.00 | Xolair [NV] |

## COUGH AND COLD PREPARATIONS

### EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

*Mucolytics*

HSD (Public)

## ▪ DORNASE ALFA

**Note** This drug is not PBS-subsidised for use in combination with PBS-subsidised mannitol.

**Note** It is highly desirable that all patients be included in the national cystic fibrosis patient database.

**Authority required (STREAMLINED)**

***5740***

Cystic fibrosis

**Population criteria:**

- Patient must be 5 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

**Authority required (STREAMLINED)**

***5634***

Cystic fibrosis

**Clinical criteria:**

- Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR
- Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR
- Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR
- Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.

**Population criteria:**

- Patient must be less than 5 years of age.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented. Treatment with this drug should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.

**Authority required (STREAMLINED)**

***5635***

Cystic fibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have initiated treatment with dornase alfa at an age of less than 5 years, **AND**
- Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

**Population criteria:**

- Patient must be 5 years of age or older.

Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

### dornase alfa 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

5704F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 2 | 5 | .. | *2242.00 | Pulmozyme [RO] |

## ▪ MANNITOL

**Note** This drug is not PBS-subsidised for use in combination with PBS-subsidised dornase alfa.

**Note** It is highly desirable that all patients be included in the national cystic fibrosis patient database.

**Authority required (STREAMLINED)**

***5799***

Cystic fibrosis

**Clinical criteria:**

- Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result, **AND**
- Patient must be intolerant or inadequately responsive to dornase alfa.

**Population criteria:**

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- Patient must be 6 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

**MANNITOL Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers, 1**

| 2015C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 4 | 5 | .. | *1736.00 | bronchitol [XA] |

# OTHER RESPIRATORY SYSTEM PRODUCTS

## OTHER RESPIRATORY SYSTEM PRODUCTS

*Other respiratory system products*

HSD (Public)

### IVACAFTOR

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Cystic fibrosis

Treatment Phase: Initial treatment - New patients

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be aged 2 years or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and

(3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and

(4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and

(5) the result of a FEV1 measurement performed within a month prior to the date of application, if aged from 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and

(6) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and

(7) a copy of a sweat chloride result; and

(8) height and weight measurements at the time of application; and

(9) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

**Authority required**

Cystic fibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be aged 2 years or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and

(3) the result of a FEV1 measurement performed within one month prior to the date of application, if aged 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and

(4) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and

(5) height and weight measurements at the time of application; and

(6) a measurement of number of days of CF-related hospitalisation (including hospital in the home) in the previous 6 months.

**ivacaftor 150 mg tablet, 56**

10170G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|
| 1 | 5 | .. | 22500.00 | Kalydeco [VR] |

## ▪ IVACAFTOR

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Cystic fibrosis

Treatment Phase: Initial treatment - New patients

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be aged 2 years or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and

(3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and

(4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and

(5) the result of a FEV1 measurement performed within a month prior to the date of application, if aged from 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and

(6) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and

(7) a copy of a sweat chloride result; and

(8) height and weight measurements at the time of application; and

(9) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Cystic fibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be aged 2 years or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

HSD (Public)

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and

(3) the result of a FEV1 measurement performed within one month prior to the date of application, if aged 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and

(4) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and

(5) height and weight measurements at the time of application; and

(6) a measurement of number of days of CF-related hospitalisation (including hospital in the home) in the previous 6 months.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Cystic fibrosis

Treatment Phase: Initial treatment - Grandfather patients

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must have received treatment with ivacaftor for this condition prior to 1 May 2017, **AND**
- Patient must have received treatment with ivacaftor within the last 6 months at the time of application, **AND**
- Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be 2 to 5 years of age.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

HSD (Public)

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort
Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin
Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.
A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.
The authority application must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Cystic Fibrosis Ivacaftor Application Supporting Information Form; and
(3) an acknowledgement signed by a parent, or authorised guardian if applicable; and
(4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene performed prior to commencing treatment with ivacaftor; and
(5) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
(6) a copy of sweat chloride result performed prior to commencing treatment with ivacaftor for this condition; and
(7) height and weight measurements at the time of application; and
(8) height and weight measurements performed immediately prior to commencement of ivacaftor; and
(9) a baseline measurement of number of days of CF-related hospitalisation (including hospital-in-the home) in the 12 months prior to commencement of ivacaftor; and
(10) a measurement of the number of days of CF-related hospitalisation (including hospital-in the home) in the 6 months prior to the date of application; and
(11) dates of prior ivacaftor therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**ivacaftor 75 mg granules, 4 x 14 sachets**

| 11098D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 5 | .. | 22500.00 | Kalydeco [VR] |

**ivacaftor 50 mg granules, 4 x 14 sachets**

| 11105L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 1 | 5 | .. | 22500.00 | Kalydeco [VR] |

# VARIOUS

## ALL OTHER THERAPEUTIC PRODUCTS

### ALL OTHER THERAPEUTIC PRODUCTS

*Iron chelating agents*

### DEFERASIROX

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**
***6420***
Chronic iron overload
**Clinical criteria:**

- Patient must have a disorder of erythropoiesis.

**deferasirox 125 mg dispersible tablet, 28**

| 5654N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 6 | 5 | .. | *1331.40 | Exjade [NV] |

**deferasirox 250 mg dispersible tablet, 28**

| 5655P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 6 | 5 | .. | *2662.74 | Exjade [NV] |

**deferasirox 500 mg dispersible tablet, 28**

| 5656Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 6 | 5 | .. | *5325.54 | Exjade [NV] |

### DEFERIPRONE

**Authority required (STREAMLINED)**

HSD (Public)

***6448***
Iron overload
**Clinical criteria:**
- Patient must have thalassaemia major, **AND**
- Patient must be unable to take desferrioxamine therapy.

**Authority required (STREAMLINED)**
***6403***
Iron overload
**Clinical criteria:**
- Patient must have thalassaemia major, **AND**
- Patient must be one in whom desferrioxamine therapy has proven ineffective.

**deferiprone 500 mg tablet, 100**

| 5657R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 6 | 5 | .. | *2568.18 | Ferriprox [TX] |

**deferiprone 100 mg/mL oral liquid, 250 mL**

| 5658T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 5 | 5 | .. | *1070.10 | Ferriprox [TX] |

## ▪ DESFERRIOXAMINE

**Authority required (STREAMLINED)**
***6394***
Disorders of erythropoiesis
**Clinical criteria:**
- The condition must be associated with treatment-related chronic iron overload.

**desferrioxamine mesilate 2 g injection, 1 vial**

| 5661Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 60 | 5 | .. | *1344.60 | Hospira Pty Limited [PF] |

**desferrioxamine mesilate 500 mg injection, 10 vials**

| 5662B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 40 | 5 | .. | *4254.80 | Hospira Pty Limited [PF] |

*Drugs for treatment of hyperkalemia and hyperphosphatemia*

## ▪ LANTHANUM

**Authority required (STREAMLINED)**
***5530***
Hyperphosphataemia
Treatment Phase: Initiation and stabilisation
**Clinical criteria:**
- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**
- Patient must be undergoing dialysis for chronic kidney disease.

**LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90**

| 5780F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *497.36 | Fosrenol [ZI] |

**LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90**

| 5782H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *845.52 | Fosrenol [ZI] |

**LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90**

| 5781G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| | 2 | 5 | .. | *751.04 | Fosrenol [ZI] |

## ▪ SEVELAMER

**Authority required (STREAMLINED)**
***5530***
Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**sevelamer hydrochloride 800 mg tablet, 180**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 9546K | 2 | 5 | .. | *589.00 | Renagel [GZ] |

## ▪ SUCROFERRIC OXYHYDROXIDE

**Authority required (STREAMLINED)**

***5530***

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**iron (as sucroferric oxyhydroxide) 500 mg tablet: chewable, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10233N | 2 | 5 | .. | *753.46 | Velphoro [FN] |

HSD (Public)

# Highly Specialised Drugs Program (Community Access)

ANTIINFECTIVES FOR SYSTEMIC USE ..... 1283

ANTIVIRALS FOR SYSTEMIC USE ..... 1283
DIRECT ACTING ANTIVIRALS ..... 1283

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS ..... 1300

IMMUNOSTIMULANTS ..... 1300
IMMUNOSTIMULANTS ..... 1300

NERVOUS SYSTEM ..... 1302

PSYCHOLEPTICS ..... 1302
ANTIPSYCHOTICS ..... 1302

# ANTIINFECTIVES FOR SYSTEMIC USE

## ANTIVIRALS FOR SYSTEMIC USE

### DIRECT ACTING ANTIVIRALS

*Nucleosides and nucleotides excl. reverse transcriptase inhibitors*

### GANCICLOVIR

**Authority required (STREAMLINED)**

***5000***

Cytomegalovirus retinitis

**Clinical criteria:**

- Patient must be severely immunocompromised, inculding due to HIV infection.

**ganciclovir 500 mg injection, 5 vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10328N | 2 | 1 | .. | *560.43 | 38.80 | Cymevene [RO] |

### VALGANCICLOVIR

**Authority required (STREAMLINED)**

***4980***

Cytomegalovirus retinitis

**Clinical criteria:**

- Patient must have HIV infection.

**valganciclovir 50 mg/mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10277X | 11 | 5 | .. | *#4396.02 | 38.80 | Valcyte [RO] |

**valganciclovir 450 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10306K | 2 | 5 | .. | *3631.45 | 38.80 | [a] Valcyte [RO]<br>[a] Valganciclovir Juno [JU]<br>[a] Valganciclovir Sandoz [SZ] | [a] Valganciclovir AN [EA]<br>[a] Valganciclovir Mylan [AF] |

*Phosphonic acid derivatives*

### FOSCARNET

**Authority required (STREAMLINED)**

***4980***

Cytomegalovirus retinitis

**Clinical criteria:**

- Patient must have HIV infection.

**Authority required (STREAMLINED)**

***4973***

Herpes simplex virus infection

**Clinical criteria:**

- The condition must be aciclovir resistant, **AND**
- Patient must have HIV infection.

**FOSCARNET SODIUM I.V. infusion 24 mg per mL, 250 mL bottle, 6**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10352W | 1 | 1 | .. | 1165.78 | 38.80 | Foscavir [LM] |

*Protease inhibitors*

### ATAZANAVIR

**Authority required (STREAMLINED)**

***4512***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

***4454***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**atazanavir 150 mg capsule, 60**

| 10276W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1038.43 | 38.80 | Reyataz [BQ] |

**atazanavir 300 mg capsule, 30**

| 10321F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1038.43 | 38.80 | Reyataz [BQ] |

**atazanavir 200 mg capsule, 60**

| 10349Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1369.33 | 38.80 | Reyataz [BQ] |

## ▪ ATAZANAVIR + COBICISTAT

**Authority required (STREAMLINED)**

***4512***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

***4454***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**atazanavir 300 mg + cobicistat 150 mg tablet, 30**

| 10692R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1116.57 | 38.80 | Evotaz [BQ] |

## ▪ DARUNAVIR

**Authority required (STREAMLINED)**

***5094***

Human immunodeficiency virus (HIV) infection

**Clinical criteria:**

- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must be co-administered with 100 mg ritonavir twice daily, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

**darunavir 600 mg tablet, 60**

| 10329P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *2039.69 | 38.80 | Prezista [JC] |

**darunavir 150 mg tablet, 240**

| 10287K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 1043.27 | 38.80 | Prezista [JC] |

## ▪ DARUNAVIR

**Authority required (STREAMLINED)**

***4313***

Human immunodeficiency virus (HIV) infection

**Clinical criteria:**

- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must be co-administered with 100 mg ritonavir, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen, **AND**

- Patient must not have demonstrated darunavir resistance associated mutations detected on resistance testing. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

**darunavir 800 mg tablet, 30**

10367P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *1375.51 | 38.80 | Prezista [JC] |

## ▪ FOSAMPRENAVIR

**Authority required (STREAMLINED)**

***4512***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

***4454***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**fosamprenavir 700 mg tablet, 60**

10337C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *756.37 | 38.80 | Telzir [VI] |

## ▪ INDINAVIR

**Authority required (STREAMLINED)**

***4512***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

***4454***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**indinavir 400 mg capsule, 180**

10363K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *906.23 | 38.80 | Crixivan 400 mg [MK] |

## ▪ RITONAVIR

**Authority required (STREAMLINED)**

***4512***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

***4454***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**ritonavir 100 mg tablet, 30**

| 10273Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 24 | 5 | .. | *978.19 | 38.80 | Norvir [VE] |

**ritonavir 600 mg/7.5 mL oral liquid, 90 mL**

| 10300D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 10 | 5 | .. | *906.25 | 38.80 | Norvir [VE] |

## ▪ SAQUINAVIR

**Authority required (STREAMLINED)**

***4512***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

***4454***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**saquinavir 500 mg tablet, 120**

| 10335Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1006.13 | 38.80 | Invirase [RO] |

## ▪ TIPRANAVIR

**Authority required (STREAMLINED)**

***5764***

HIV infection

**Clinical criteria:**

- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- Patient must be antiretroviral experienced, **AND**
- The treatment must be co-administered with 200 mg ritonavir twice daily, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

**tipranavir 250 mg capsule, 120**

| 10344K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1675.07 | 38.80 | Aptivus [BY] |

*Nucleoside and nucleotide reverse transcriptase inhibitors*

## ▪ ABACAVIR

**Authority required (STREAMLINED)**

***4512***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

***4454***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**abacavir 300 mg tablet, 60**

| 10294T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *564.39 | 38.80 | Ziagen [VI] |

**abacavir 20 mg/mL oral liquid, 240 mL**

| 10356C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 8 | 5 | .. | *656.35 | 38.80 | Ziagen [VI] |

## ▪ ADEFOVIR DIPIVOXIL

**Note** Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

**Authority required (STREAMLINED)**

***4490***

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must not have cirrhosis, **AND**
- Patient must have failed antihepadnaviral therapy, **AND**
- Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR
- Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.

**Authority required (STREAMLINED)**

***4510***

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must have cirrhosis, **AND**
- Patient must have failed antihepadnaviral therapy, **AND**
- Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**adefovir dipivoxil 10 mg tablet, 30**

| 10290N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1097.15 | 38.80 | [a] APO-Adefovir [TX] | [a] Hepsera [GI] |

## ▪ DIDANOSINE

**Authority required (STREAMLINED)**

***4512***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

***4454***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**didanosine 400 mg enteric capsule, 30**

| 10313T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *652.89 | 38.80 | Videx EC [BQ] |

**didanosine 250 mg enteric capsule, 30**

| 10364L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *410.73 | 38.80 | Videx EC [BQ] |

## ▪ EMTRICITABINE

**Authority required (STREAMLINED)**

***4512***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

***4454***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**emtricitabine 200 mg capsule, 30**

10274R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *564.39 | 38.80 | Emtriva [GI] |

## ▪ ENTECAVIR

**Authority required (STREAMLINED)**

***4993***

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must not have cirrhosis, **AND**
- Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR
- Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, **AND**
- Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.

**Authority required (STREAMLINED)**

***5036***

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must have cirrhosis, **AND**
- Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**entecavir monohydrate 500 microgram tablet, 30**

10279B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *645.05 | 38.80 | [a] Baraclude [BQ] | [a] ENTAC [LR] |
| | | | | | [a] Entecavir Amneal [EA] | [a] Entecavir APOTEX [TX] |
| | | | | | [a] Entecavir GH [GQ] | [a] Entecavir Mylan [AF] |
| | | | | | [a] ENTECAVIR RBX [RA] | [a] Entecavir Sandoz [SZ] |
| | | | | | [a] ENTECLUDE [RW] | |

## ▪ ENTECAVIR

**Note** PBS-subsidised entecavir monohydrate must be used as monotherapy.

**Authority required (STREAMLINED)**

***5044***

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must not have cirrhosis, **AND**
- Patient must have failed lamivudine, **AND**
- Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR
- Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.

**Authority required (STREAMLINED)**

***5037***

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must have cirrhosis, **AND**
- Patient must have failed lamivudine, **AND**
- Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**entecavir monohydrate 1 mg tablet, 30**

| 10353X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1044.55 | 38.80 | [a] Baraclude [BQ]<br>[a] Entecavir Amneal [EA]<br>[a] Entecavir GH [GQ]<br>[a] ENTECAVIR RBX [RA]<br>[a] ENTECLUDE [RW] | [a] ENTAC [LR]<br>[a] Entecavir APOTEX [TX]<br>[a] Entecavir Mylan [AF]<br>[a] Entecavir Sandoz [SZ] |

## ▪ LAMIVUDINE

**Authority required (STREAMLINED)**

***4512***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

***4454***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**lamivudine 10 mg/mL oral liquid, 240 mL**

| 10320E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 8 | 5 | .. | *472.91 | 38.80 | 3TC [VI] |

**lamivudine 300 mg tablet, 30**

| 10311Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *143.41 | 38.80 | [a] 3TC [VI] | [a] Lamivudine Alphapharm [AF] |

**lamivudine 150 mg tablet, 60**

| 10348P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *143.41 | 38.80 | [a] 3TC [VI] | [a] Lamivudine Alphapharm [AF] |

## ▪ LAMIVUDINE

**Authority required (STREAMLINED)**

***4993***

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must not have cirrhosis, **AND**
- Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR
- Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, **AND**
- Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.

**Authority required (STREAMLINED)**

***5036***

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must have cirrhosis, **AND**
- Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**lamivudine 100 mg tablet, 28**

| 10315X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *80.55 | 38.80 | [a] Zetlam [AF] |
| | | | [B] 1.20 | *81.75 | 38.80 | [a] Zeffix [RW] |

**lamivudine 5 mg/mL oral liquid, 240 mL**

| 10338D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 5 | 5 | .. | *242.45 | 38.80 | Zeffix [RW] |

## ▪ STAVUDINE

**Authority required (STREAMLINED)**

***4512***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

***4454***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**stavudine 30 mg capsule, 60**

10271N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *666.51 | 38.80 | Zerit [BQ] |

**stavudine 40 mg capsule, 60**

10312R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *886.29 | 38.80 | Zerit [BQ] |

HSD (Community)

## ▪ TENOFOVIR

**Note** Pharmaceutical benefits that have the forms tenofovir disoproxil phosphate 291 mg tablet, tenofovir disoproxil maleate 300 mg tablet, and tenofovir disoproxil fumarate 300 mg tablet are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

***6998***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

***6982***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

***6980***

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must have cirrhosis, **AND**
- Patient must be nucleoside analogue naive, **AND**
- Patient must have detectable HBV DNA, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**Note** Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

**Authority required (STREAMLINED)**

***6992***

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must not have cirrhosis, **AND**
- Patient must be nucleoside analogue naive, **AND**
- Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR
- Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, **AND**
- Patient must have evidence of chronic liver injury determined by: (i) confirmed elevated serum ALT; or (ii) liver biopsy, **AND**

- The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

**Authority required (STREAMLINED)**

***6983***

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must have cirrhosis, **AND**
- Patient must have failed antihepadnaviral therapy, **AND**
- Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**Note** Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

**Authority required (STREAMLINED)**

***6984***

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must not have cirrhosis, **AND**
- Patient must have failed antihepadnaviral therapy, **AND**
- Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR
- Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.

**Note** Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

**tenofovir disoproxil fumarate 300 mg tablet, 30**

| 10310P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *809.03 | 38.80 | [a] Viread [GI] |

**tenofovir disoproxil maleate 300 mg tablet, 30**

| 11155D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *809.03 | 38.80 | [a] Tenofovir Disoproxil Mylan [AF] |

**tenofovir disoproxil phosphate 291 mg tablet, 30**

| 11142K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *809.03 | 38.80 | [a] Tenofovir GH [GQ] |

## ▪ ZIDOVUDINE

**Authority required (STREAMLINED)**

***4512***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

***4454***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**zidovudine 50 mg/5 mL oral liquid, 200 mL**

| 10361H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 15 | 5 | .. | *672.40 | 38.80 | Retrovir [VI] |

**zidovudine 250 mg capsule, 40**

| 10360G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 6 | 5 | .. | *1218.31 | 38.80 | Retrovir [VI] |

**zidovudine 100 mg capsule, 100**

| 10266H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | 5 | .. | *819.15 | 38.80 | Retrovir [VI] |

*Non-nucleoside reverse transcriptase inhibitors*

## ▪ EFAVIRENZ

**Authority required (STREAMLINED)**

***4512***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

***4454***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**efavirenz 30 mg/mL oral liquid, 180 mL**

| 10275T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 7 | 5 | .. | *570.65 | 38.80 | Stocrin [MK] |

**efavirenz 200 mg tablet, 90**

| 10336B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *543.79 | 38.80 | Stocrin [MK] |

**efavirenz 600 mg tablet, 30**

| 10366N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *543.79 | 38.80 | Stocrin [MK] |

## ▪ ETRAVIRINE

**Authority required (STREAMLINED)**

***5014***

HIV infection

**Clinical criteria:**

- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- Patient must be antiretroviral experienced, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

**etravirine 200 mg tablet, 60**

| 10301E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1218.51 | 38.80 | Intelence [JC] |

## ▪ NEVIRAPINE

**Authority required (STREAMLINED)**

***4526***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have been stabilised on nevirapine immediate release, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

***4454***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**nevirapine 400 mg modified release tablet, 30**

10303G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *334.01 | 38.80 | [a] Nevirapine XR APOTEX [TX] | [a] Viramune XR [BY] |

## ▪ NEVIRAPINE

**Authority required (STREAMLINED)**

***4512***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

***4454***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**nevirapine 10 mg/mL oral liquid, 240 mL**

10319D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10 | 5 | .. | *1397.15 | 38.80 | Viramune [BY] |

**nevirapine 200 mg tablet, 60**

10304H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *334.01 | 38.80 | [a] Nevirapine Alphapharm [AF] | [a] Viramune [BY] |

## ▪ RILPIVIRINE

**Authority required (STREAMLINED)**

***4512***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

***4454***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**rilpivirine 25 mg tablet, 30**

10298B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *543.79 | 38.80 | Edurant [JC] |

*Antivirals for treatment of HIV infections, combinations*

## ▪ ABACAVIR + LAMIVUDINE

**Authority required (STREAMLINED)**

***4527***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Population criteria:**

- Patient must be aged 12 years or older, **AND**
- Patient must weigh 40 kg or more.

**Authority required (STREAMLINED)**

***4528***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Population criteria:**

- Patient must be aged 12 years or older, **AND**
- Patient must weigh 40 kg or more.

**abacavir 600 mg + lamivudine 300 mg tablet, 30**

10357D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *700.65 | 38.80 | Kivexa [VI] |

## ▪ ABACAVIR + LAMIVUDINE + ZIDOVUDINE

**Authority required (STREAMLINED)**

***4495***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive.

**Population criteria:**

- Patient must be aged 12 years or older, **AND**
- Patient must weigh 40 kg or more.

**Authority required (STREAMLINED)**

***4480***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection.

**Population criteria:**

- Patient must be aged 12 years or older, **AND**
- Patient must weigh 40 kg or more.

**abacavir 300 mg + lamivudine 150 mg + zidovudine 300 mg tablet, 60**

10305J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *1123.43 | 38.80 | Trizivir [VI] |

## ▪ DARUNAVIR + COBICISTAT

**Authority required (STREAMLINED)**

***6413***

Human immunodeficiency virus (HIV) infection

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must not be in combination with ritonavir.

**Note** The cobicistat component of the darunavir + cobicistat combination product provides the necessary pharmacokinetic enhancement of darunavir to achieve therapeutic levels of darunavir.

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**Authority required (STREAMLINED)**

***6428***

Human immunodeficiency virus (HIV) infection

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must not be in combination with ritonavir.

**Note** The cobicistat component of the darunavir + cobicistat combination product provides the necessary pharmacokinetic enhancement of darunavir to achieve therapeutic levels of darunavir.

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**Authority required (STREAMLINED)**

***6377***

Human immunodeficiency virus (HIV) infection

**Clinical criteria:**

- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must not be in combination with ritonavir, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

**Note** The cobicistat component of the darunavir + cobicistat combination product provides the necessary pharmacokinetic enhancement of darunavir to achieve therapeutic levels of darunavir.

**darunavir 800 mg + cobicistat 150 mg tablet, 30**

| 10903W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1341.39 | 38.80 | Prezcobix [JC] |

## ▪ DOLUTEGRAVIR + ABACAVIR + LAMIVUDINE

**Authority required (STREAMLINED)**

***4495***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive.

**Population criteria:**

- Patient must be aged 12 years or older, **AND**
- Patient must weigh 40 kg or more.

**Authority required (STREAMLINED)**

***4480***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection.

**Population criteria:**

- Patient must be aged 12 years or older, **AND**
- Patient must weigh 40 kg or more.

**dolutegravir 50 mg + abacavir 600 mg + lamivudine 300 mg tablet, 30**

| 10345L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1928.55 | 38.80 | Triumeq [VI] |

## ▪ EMTRICITABINE + RILPIVIRINE + TENOFOVIR ALAFENAMIDE

**Authority required (STREAMLINED)**

***4522***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive.

**Authority required (STREAMLINED)**

***4470***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection.

**emtricitabine 200 mg + rilpivirine 25 mg + tenofovir alafenamide 25 mg tablet, 30 tablets**

| 11104K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *2016.85 | 38.80 | Odefsey [GI] |

## ▪ EMTRICITABINE + TENOFOVIR ALAFENAMIDE

**Authority required (STREAMLINED)**

***4512***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

***4454***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**emtricitabine 200 mg + tenofovir alafenamide 10 mg tablet, 30**

| 11099E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1500.85 | 38.80 | Descovy [GI] |

**emtricitabine 200 mg + tenofovir alafenamide 25 mg tablet, 30**

| 11113X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1500.85 | 38.80 | Descovy [GI] |

## ▪ LAMIVUDINE + ZIDOVUDINE

**Authority required (STREAMLINED)**

***4512***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

***4454***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

HSD (Community)

**lamivudine 150 mg + zidovudine 300 mg tablet, 60**

| 10284G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *580.57 | 38.80 | [a] Combivir [VI] | [a] Lamivudine 150 mg + Zidovudine 300 mg Alphapharm [AF] |

## ▪ LOPINAVIR + RITONAVIR

**Authority required (STREAMLINED)**

***4512***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

***4454***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**lopinavir 200 mg + ritonavir 50 mg tablet, 120**

| 10272P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1408.93 | 38.80 | Kaletra [VE] |

**lopinavir 100 mg + ritonavir 25 mg tablet, 60**

| 10285H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *361.21 | 38.80 | Kaletra [VE] |

**lopinavir 400 mg/5 mL + ritonavir 100 mg/5 mL oral liquid, 60 mL**

| 10327M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 10 | 5 | .. | *1329.55 | 38.80 | Kaletra [VE] |

## ▪ TENOFOVIR + EMTRICITABINE

**Note** Pharmaceutical benefits that have the forms tenofovir disoproxil phosphate 291 mg with emtricitabine 200 mg tablet, tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg tablet, and tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg tablet are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

***6985***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

***6986***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30**

| 10347N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1268.25 | 38.80 | [a] Truvada [GI] |

**tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg tablet, 30**

| 11149T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1268.25 | 38.80 | [a] Tenofovir Disoproxil Emtricitabine Mylan 300/200 [AF] |

**tenofovir disoproxil phosphate 291 mg + emtricitabine 200 mg tablet, 30**

| 11146P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1268.25 | 38.80 | [a] Tenofovir EMT GH [GQ] |

## ▪ TENOFOVIR + EMTRICITABINE + EFAVIRENZ

**Authority required (STREAMLINED)**

***4522***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive.

**Authority required (STREAMLINED)**

***4470***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection.

**tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + efavirenz 600 mg tablet, 30**

| 10297Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1784.25 | 38.80 | Atripla [GI] |

## ▪ TENOFOVIR + EMTRICITABINE + ELVITEGRAVIR + COBICISTAT

**Authority required (STREAMLINED)**

***4522***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive.

**Authority required (STREAMLINED)**

***4470***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection.

**tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + elvitegravir 150 mg + cobicistat 150 mg tablet, 30**

| 10307L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1784.25 | 38.80 | Stribild [GI] |

## ▪ TENOFOVIR + EMTRICITABINE + RILPIVIRINE

**Authority required (STREAMLINED)**

***4522***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive.

**Authority required (STREAMLINED)**

***4470***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection.

**tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + rilpivirine 25 mg tablet, 30**

| 10314W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1784.25 | 38.80 | Eviplera [GI] |

## ▪ TENOFOVIR ALAFENAMIDE + EMTRICITABINE + ELVITEGRAVIR + COBICISTAT

**Authority required (STREAMLINED)**

***4522***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive.

**Authority required (STREAMLINED)**

***4470***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection.

**tenofovir alafenamide 10 mg + emtricitabine 200 mg + elvitegravir 150 mg + cobicistat 150 mg tablet, 30**

| 11114Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *2016.85 | 38.80 | Genvoya [GI] |

HSD (Community)

*Other antivirals*

## ▪ DOLUTEGRAVIR

**Authority required (STREAMLINED)**

***4512***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

***4454***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**dolutegravir 50 mg tablet, 30**

| 10283F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1378.25 | 38.80 | Tivicay [VI] |

## ▪ ENFUVIRTIDE

**Authority required (STREAMLINED)**

***5014***

HIV infection

**Clinical criteria:**

- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- Patient must be antiretroviral experienced, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

**enfuvirtide 90 mg injection [60 vials] (&) inert substance diluent [60 x 1.1 mL vials], 1 pack**

| 10365M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *4251.85 | 38.80 | Fuzeon [RO] |

## ▪ MARAVIROC

**Authority required (STREAMLINED)**

***5008***

HIV infection

**Clinical criteria:**

- Patient must be infected with CCR5-tropic HIV-1, **AND**
- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

A tropism assay to determine CCR5 only strain status must be performed prior to initiation. Individuals with CXCR4 tropism demonstrated at any time point are not eligible.

**maraviroc 150 mg tablet, 60**

| 10318C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1790.79 | 38.80 | Celsentri [VI] |

**maraviroc 300 mg tablet, 60**

| 10355B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1790.79 | 38.80 | Celsentri [VI] |

## ▪ RALTEGRAVIR

**Authority required (STREAMLINED)**

***4512***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

***4454***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**raltegravir 400 mg tablet, 60**

| 10286J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1311.69 | 38.80 | Isentress [MK] |

## ▪ RALTEGRAVIR

**Authority required (STREAMLINED)**

***4275***

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- The treatment must be in combination with other antiretroviral agents, **AND**
- Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy, **AND**
- Patient must have a CD4 count of less than 500 per cubic millimetre; OR
- Patient must have symptomatic HIV disease.

**Population criteria:**

- Patient must be aged 2 years or older.

**Authority required (STREAMLINED)**

***4274***

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- The treatment must be in combination with other antiretroviral agents, **AND**

- Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy, **AND**
- Patient must have previously received PBS-subsidised therapy for HIV infection.

**Population criteria:**

- Patient must be aged 2 years or older.

**raltegravir 100 mg chewable tablet, 60**

10326L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 6 | 5 | .. | *1970.95 | 38.80 | Isentress [MK] |

**raltegravir 25 mg chewable tablet, 60**

10299C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 6 | 5 | .. | *507.37 | 38.80 | Isentress [MK] |

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

## IMMUNOSTIMULANTS

### IMMUNOSTIMULANTS

*Interferons*

### INTERFERON ALFA-2A

**Authority required (STREAMLINED)**

***4993***

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must not have cirrhosis, **AND**
- Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR
- Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, **AND**
- Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.

**Authority required (STREAMLINED)**

***5036***

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must have cirrhosis, **AND**
- Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe**

10317B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 30 | 5 | .. | *890.35 | 38.80 | Roferon-A [RO] |

**interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe**

10369R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 30 | 5 | .. | *2594.35 | 38.80 | Roferon-A [RO] |

### INTERFERON ALFA-2B

**Authority required (STREAMLINED)**

***4993***

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must not have cirrhosis, **AND**
- Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR
- Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, **AND**
- Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.

**Authority required (STREAMLINED)**

***5036***

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must have cirrhosis, **AND**
- Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**interferon alfa-2b 30 million units/1.2 mL injection, 1.2 mL**

| 10316Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *595.81 | 38.80 | Intron A Redipen [MK] |

**interferon alfa-2b 60 million units/1.2 mL injection, 1.2 mL**

| 10292Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *1179.17 | 38.80 | Intron A Redipen [MK] |

**interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL**

| 10291P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *360.33 | 38.80 | Intron A Redipen [MK] |

**interferon alfa-2b 18 million units/3 mL injection, 3 mL vial**

| 10340F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 15 | 5 | .. | *2594.20 | 38.80 | Intron A [MK] |

**interferon alfa-2b 10 million units/mL injection, 5 x 1 mL vials**

| 10370T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 5 | .. | *1462.18 | 38.80 | Intron A [MK] |

**interferon alfa-2b 25 million units/2.5 mL injection, 2.5 mL vial**

| 10339E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 15 | 5 | .. | *3584.80 | 38.80 | Intron A [MK] |



## ▪ PEGINTERFERON ALFA-2A

**Caution** Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required (STREAMLINED)**

***5010***

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must not have cirrhosis, **AND**
- Patient must not have previously received peginterferon alfa therapy for the treatment of hepatitis B, **AND**
- Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR
- Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, **AND**
- Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Authority required (STREAMLINED)**

***5067***

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must have cirrhosis, **AND**
- Patient must have detectable HBV DNA, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be limited to 1 course of treatment for a maximum duration of 48 weeks.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

| 10278Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *2612.59 | 38.80 | Pegasys [RO] |

**peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

| 10280C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *2262.37 | 38.80 | Pegasys [RO] |

# NERVOUS SYSTEM

## PSYCHOLEPTICS

### ANTIPSYCHOTICS

*Diazepines, oxazepines, thiazepines and oxepines*

## CLOZAPINE

**Note** Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Novartis Clozaril Patient Monitoring System (eCPMS) or Hospira Clopineconnect.

**Authority required (STREAMLINED)**

***4998***

Schizophrenia

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a psychiatrist; OR
- Must be treated by an authorised medical practitioner, with the agreement of the treating psychiatrist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy with this drug for this condition, **AND**
- Patient must have completed at least 18 weeks therapy, **AND**
- Patient must be on a clozapine dosage considered stable by a treating psychiatrist, **AND**
- The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

HSD (Community)

**clozapine 200 mg tablet, 100**

| 10288L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *511.31 | 38.80 | Clopine 200 [PF] |

**clozapine 25 mg tablet, 100**

| 10289M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | .. | .. | *75.79 | 38.80 | [a] Clopine 25 [PF] | [a] Clozaril 25 [NV] |

**clozapine 50 mg tablet, 100**

| 10302F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *141.61 | 38.80 | Clopine 50 [PF] |

**clozapine 100 mg tablet, 100**

| 10358E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | .. | .. | *259.23 | 38.80 | [a] Clopine 100 [PF] | [a] Clozaril 100 [NV] |

**clozapine 50 mg/mL oral liquid, 100 mL**

| 10341G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 147.55 | 38.80 | Clopine Suspension [PF] |

# Botulinum Toxin Program

MUSCULO-SKELETAL SYSTEM ..... 1304

MUSCLE RELAXANTS ..... 1304

MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS ..... 1304

# MUSCULO-SKELETAL SYSTEM

## MUSCLE RELAXANTS

### MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS

*Other muscle relaxants, peripherally acting agents*

### BOTULINUM TOXIN TYPE A

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

***5221***

Blepharospasm or hemifacial spasm

**Clinical criteria:**

- Patient must have blepharospasm; OR
- Patient must have hemifacial spasm.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an ophthalmologist; OR
- Must be treated by an otolaryngology head and neck surgeon; OR
- Must be treated by a plastic surgeon.

**Population criteria:**

- Patient must be aged 12 years or older.

**botulinum toxin type A 100 units injection, 1 vial**

10997T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | .. | .. | *1626.07 | 38.80 | Botox [AG] |

### BOTULINUM TOXIN TYPE A

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.



**Authority required (STREAMLINED)**

***5406***

Spasmodic torticollis

**Clinical criteria:**

- Patient must have spasmodic torticollis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be as adjunctive therapy to current standard care.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a rehabilitation specialist.

**botulinum toxin type A 100 units injection, 1 vial**

11023E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | .. | .. | *1626.07 | 38.80 | Botox [AG] |

### BOTULINUM TOXIN TYPE A

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***5409***

Urinary incontinence

**Clinical criteria:**

- The condition must be due to neurogenic detrusor overactivity, as demonstrated by urodynamic study, **AND**
- The condition must be inadequately controlled by anti-cholinergic therapy, **AND**
- Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with Botulinum Toxin Type A Neurotoxin Complex, **AND**
- Patient must be willing and able to self-catheterise, **AND**
- The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment, **AND**
- Patient must have multiple sclerosis; OR
- Patient must have a spinal cord injury; OR
- Patient must be aged 18 years or older and have spina bifida.

**Treatment criteria:**

- Must be treated by a urologist; OR
- Must be treated by a urogynaecologist.

**botulinum toxin type A 100 units injection, 1 vial**

| 10993N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | .. | .. | *1626.07 | 38.80 | Botox [AG] |

## ▪ BOTULINUM TOXIN TYPE A

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

***5359***

Dynamic equinus foot deformity

**Clinical criteria:**

- The condition must be due to spasticity, **AND**
- Patient must have cerebral palsy, **AND**
- Patient must be ambulant.

**Population criteria:**

- Patient must be aged from 2 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

**Authority required (STREAMLINED)**

***5407***

Dynamic equinus foot deformity

**Clinical criteria:**

- The condition must be due to spasticity, **AND**
- Patient must have cerebral palsy, **AND**
- Patient must be ambulant, **AND**
- Patient must have commenced PBS-subsidised treatment with Botulinum Toxin Type A Purified Neurotoxin Complex as a paediatric patient.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

**botulinum toxin type A 100 units injection, 1 vial**

| 10998W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | .. | .. | *1626.07 | 38.80 | Botox [AG] |

## ▪ BOTULINUM TOXIN TYPE A

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***5262***

Chronic migraine

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with botulinum toxin type A neurotoxin, **AND**
- Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with botulinum toxin type A neurotoxin, **AND**
- Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of headache days per month after two treatment cycles (each of 12 weeks duration) in order to be eligible for continuing PBS-subsidised treatment, **AND**
- Patient must be appropriately managed by his or her practitioner for medication overuse headache, prior to initiation of treatment with botulinum toxin.

**Population criteria:**

- Patient must be aged 18 years or older.

Prophylactic migraine medications are propanolol, amitriptylin, methsergide, pizotifen, cyproheptadine or topiramate.

**botulinum toxin type A 100 units injection, 1 vial**

| 11000Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | .. | .. | *1626.07 | 38.80 | Botox [AG] |

## ▪ BOTULINUM TOXIN TYPE A

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***6953***

Urinary incontinence

**Treatment criteria:**

- Must be treated by a urologist; OR
- Must be treated by a gynaecologist.

**Clinical criteria:**

- The condition must be due to idiopathic overactive bladder, **AND**
- The condition must have been inadequately controlled by therapy involving at least two alternative anti-cholinergic agents, **AND**
- Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with botulinum toxin type A neurotoxin complex, **AND**
- Patient must be willing and able to self-catheterise, **AND**
- The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

**botulinum toxin type A 100 units injection, 1 vial**

| 11004E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | .. | .. | *1626.07 | 38.80 | Botox [AG] |



## ▪ BOTULINUM TOXIN TYPE A

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***5408***

Severe primary axillary hyperhidrosis

**Clinical criteria:**

- Patient must have previously failed topical aluminium chloride hexahydrate after one to two months of treatment; OR
- Patient must be intolerant to topical aluminium chloride hexahydrate treatment.

**Population criteria:**

- Patient must be aged 12 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist; OR
- Must be treated by a neurologist; OR
- Must be treated by a paediatrician.

Maximum number of treatments per year is 3, with no less than 4 months to elapse between treatments.

**botulinum toxin type A 100 units injection, 1 vial**

| 11016T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | .. | .. | *1626.07 | 38.80 | Botox [AG] |

## ▪ BOTULINUM TOXIN TYPE A

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

***5178***

Moderate to severe spasticity of the upper limb

**Clinical criteria:**

- Patient must have cerebral palsy.

**Population criteria:**

- Patient must be aged from 2 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR

- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon.

**Authority required (STREAMLINED)**

***5261***

Moderate to severe spasticity of the upper limb

**Clinical criteria:**

- Patient must have cerebral palsy, **AND**
- Patient must have commenced PBS-subsidised treatment with Botulinum Type A Neurotoxin Complex as a paediatric patient.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon.

**Note** Contact the Department of Human Services before commencing PBS-subsidised treatment in cerebral palsy patients who have been treated for moderate to severe spasticity of the upper limb with non-PBS-subsidised botulinum toxin prior to the age of 18.

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**Authority required (STREAMLINED)**

***5220***

Moderate to severe spasticity of the upper limb following a stroke

**Clinical criteria:**

- The condition must be moderate to severe spasticity of the upper limb/s following stroke, defined as a Modified Ashworth Scale rating of 3 or more, **AND**
- The treatment must not be initiated until three months post-stroke, **AND**
- The treatment must only be used as second line therapy when standard management has failed; OR
- The treatment must only be used as an adjunct to physical therapy, **AND**
- The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (total Botox, Dysport, and Xeomin), **AND**
- The treatment must not exceed 4 treatment periods (total Botox, Dysport, and Xeomin) per upper limb per lifetime, **AND**
- Patient must not have established severe contracture in the limb to be treated.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a geriatrician.

The date of the stroke must be documented in the patient's medical records when treatment is initiated.

Standard management includes physiotherapy and/or oral spasticity agents.

**botulinum toxin type A 100 units injection, 1 vial**

10999X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | .. | .. | *1626.07 | 38.80 | Botox [AG] |

## ▪ CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

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**Authority required (STREAMLINED)**

***5220***

Moderate to severe spasticity of the upper limb following a stroke

**Clinical criteria:**

- The condition must be moderate to severe spasticity of the upper limb/s following stroke, defined as a Modified Ashworth Scale rating of 3 or more, **AND**
- The treatment must not be initiated until three months post-stroke, **AND**
- The treatment must only be used as second line therapy when standard management has failed; OR
- The treatment must only be used as an adjunct to physical therapy, **AND**
- The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (total Botox, Dysport, and Xeomin), **AND**
- The treatment must not exceed 4 treatment periods (total Botox, Dysport, and Xeomin) per upper limb per lifetime, **AND**
- Patient must not have established severe contracture in the limb to be treated.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a geriatrician.

The date of the stroke must be documented in the patient's medical records when treatment is initiated.

Standard management includes physiotherapy and/or oral spasticity agents.

**clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial**

| 10988H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *1272.29 | 38.80 | Dysport [IS] |

**clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial**

| 10982B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | .. | .. | *1420.91 | 38.80 | Dysport [IS] |

## ▪ CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

***5405***

Blepharospasm or hemifacial spasm

**Clinical criteria:**

- Patient must have blepharospasm; OR
- Patient must have hemifacial spasm.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an ophthalmologist; OR
- Must be treated by an otolaryngology head and neck surgeon; OR
- Must be treated by a plastic surgeon.



**clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial**

| 11022D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *1272.29 | 38.80 | Dysport [IS] |

**clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial**

| 10987G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | .. | .. | *1420.91 | 38.80 | Dysport [IS] |

## ▪ CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

***5406***

Spasmodic torticollis

**Clinical criteria:**

- Patient must have spasmodic torticollis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be as adjunctive therapy to current standard care.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a rehabilitation specialist.

**clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial**

| 11015R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *1272.29 | 38.80 | Dysport [IS] |

**clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial**

| 11007H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | .. | .. | *1420.91 | 38.80 | Dysport [IS] |

## ▪ CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

***5359***

Dynamic equinus foot deformity

**Clinical criteria:**

- The condition must be due to spasticity, **AND**
- Patient must have cerebral palsy, **AND**
- Patient must be ambulant.

**Population criteria:**

- Patient must be aged from 2 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

**Authority required (STREAMLINED)**

***5332***

Dynamic equinus foot deformity

**Clinical criteria:**

- The condition must be due to spasticity, **AND**
- Patient must be an ambulant cerebral palsy patient, **AND**
- Patient must have commenced on PBS-subsidised treatment with clostridium botulinum type A toxin-haemagglutinin complex as a paediatric patient.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

**clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial**

11006G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *1272.29 | 38.80 | Dysport [IS] |

**clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial**

10981Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | .. | .. | *1420.91 | 38.80 | Dysport [IS] |

## ▪ INCOBOTULINUMTOXINA

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

***5220***

Moderate to severe spasticity of the upper limb following a stroke

**Clinical criteria:**

- The condition must be moderate to severe spasticity of the upper limb/s following stroke, defined as a Modified Ashworth Scale rating of 3 or more, **AND**
- The treatment must not be initiated until three months post-stroke, **AND**
- The treatment must only be used as second line therapy when standard management has failed; OR
- The treatment must only be used as an adjunct to physical therapy, **AND**
- The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (total Botox, Dysport, and Xeomin), **AND**
- The treatment must not exceed 4 treatment periods (total Botox, Dysport, and Xeomin) per upper limb per lifetime, **AND**
- Patient must not have established severe contracture in the limb to be treated.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a geriatrician.

The date of the stroke must be documented in the patient's medical records when treatment is initiated.
Standard management includes physiotherapy and/or oral spasticity agents.

**incobotulinumtoxinA 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial**

10983C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | .. | .. | *1547.15 | 38.80 | Xeomin [EZ] |

## ▪ INCOBOTULINUMTOXINA

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

***5360***

Blepharospasm

**Clinical criteria:**

- Patient must have blepharospasm.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an ophthalmologist; OR
- Must be treated by an otolaryngology head and neck surgeon; OR
- Must be treated by a plastic surgeon.

**incobotulinumtoxinA 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial**

10994P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | .. | .. | *1547.15 | 38.80 | Xeomin [EZ] |

## ▪ INCOBOTULINUMTOXINA

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

***5222***

Spasmodic torticollis

**Clinical criteria:**

- Patient must have spasmodic torticollis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be as adjunctive therapy to current standard care.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a rehabilitation specialist.

**Population criteria:**

- Patient must be aged 18 years or older.

**incobotulinumtoxinA 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial**

11005F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | .. | .. | *1547.15 | 38.80 | Xeomin [EZ] |

# Growth Hormone Program

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.....1312

PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES..... 1312
ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES..... 1312

# ▪ SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

## ▪ PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

### ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES

*Somatropin and somatropin agonists*

### ▪ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; OR
- Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation of the patient's maturational or constitutional delay status; AND

6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Confirmation that the patient has precocious puberty; AND

7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity above the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of greater than 8 cm per year, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

8. Confirmation that the patient has hypothalamic obesity; AND

9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height at or below the 95$^{th}$ percentile for age on the Turner syndrome growth curve for girls, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height at or below the 25th percentile for age and sex, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ ; AND

6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge**

| 10518N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 223.37 | 38.80 | Omnitrope Surepal 5 [SZ] |

**somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge**

| 10514J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 439.58 | 38.80 | Omnitrope Surepal 10 [SZ] |

**somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge**

| 6311E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 439.58 | 38.80 | Omnitrope [SZ] |

**somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge**

| 10446T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 655.80 | 38.80 | Omnitrope Surepal 15 [SZ] |

## ▪ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; OR
- Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation of the patient's maturational or constitutional delay status; AND

6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven

biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Confirmation that the patient has precocious puberty; AND

7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven

biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity above the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of greater than 8 cm per year, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

8. Confirmation that the patient has hypothalamic obesity; AND

9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height at or below the 95$^{th}$ percentile for age on the Turner syndrome growth curve for girls, **AND**

- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**somatropin 12 units (4 mg) injection [1 vial] (&) inert substance diluent [1 vial], 1 pack**

6266T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 180.12 | 38.80 | Zomacton [FP] |

**somatropin 30 units (10 mg) injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack**

6310D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 439.58 | 38.80 | Zomacton [FP] |

## ▪ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

GH

**Authority required**

Short stature and slow growth

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; OR

- Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation of the patient's maturational or constitutional delay status; AND

6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.



**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Confirmation that the patient has precocious puberty; AND

7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity above the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of greater than 8 cm per year, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

8. Confirmation that the patient has hypothalamic obesity; AND

9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height at or below the 95$^{th}$ percentile for age on the Turner syndrome growth curve for girls, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height at or below the 25th percentile for age and sex, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ ; AND

6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**somatropin 60 units (20 mg/2.5 mL) injection, 2.5 mL cartridge**

| 3388H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 872.01 | 38.80 | Saizen [SG] |

**somatropin 18 units (6 mg/1.03 mL) injection, 1.03 mL cartridge**

| 5822K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 266.61 | 38.80 | Saizen [SG] |

**somatropin 36 units (12 mg/1.5 mL) injection, 1.5 mL cartridge**

| 5824M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 526.07 | 38.80 | Saizen [SG] |

## ▪ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; OR
- Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation of the patient's maturational or constitutional delay status; AND

6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**

- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Confirmation that the patient has precocious puberty; AND

7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity above the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of greater than 8 cm per year, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

8. Confirmation that the patient has hypothalamic obesity; AND

9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height at or below the 95$^{th}$ percentile for age on the Turner syndrome growth curve for girls, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height at or below the 25th percentile for age and sex, **AND**

- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ ; AND

6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge**

| 5818F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 223.37 | 38.80 | Norditropin FlexPro [NO] |

**somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge**

| 6295H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 223.37 | 38.80 | Norditropin SimpleXx [NO] |

**somatropin 30 units (10 mg/2 mL) injection, 2 mL cartridge**

| 9604L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 439.58 | 38.80 | NutropinAq [IS] |

**somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge**

| 5819G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 439.58 | 38.80 | Norditropin FlexPro [NO] |

**somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge**

| 6296J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 439.58 | 38.80 | Norditropin SimpleXx [NO] |

**somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge**

| 5820H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 655.80 | 38.80 | Norditropin FlexPro [NO] |

**somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge**

| 6297K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 655.80 | 38.80 | Norditropin SimpleXx [NO] |

## ▪ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; OR
- Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation of the patient's maturational or constitutional delay status; AND

6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine,

clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Confirmation that the patient has precocious puberty; AND

7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine,

clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity above the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of greater than 8 cm per year, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

8. Confirmation that the patient has hypothalamic obesity; AND

9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height at or below the 95$^{th}$ percentile for age on the Turner syndrome growth curve for girls,

**AND**

- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**

- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height at or below the 25th percentile for age and sex, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be prepubertal.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ ; AND

6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**somatropin 36 units (12 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack**

| 6170R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 526.07 | 38.80 | Humatrope [LY] |

**somatropin 72 units (24 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack**

| 6345Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 1044.99 | 38.80 | Humatrope [LY] |

**somatropin 18 units (6 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack**

| 6169Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 266.61 | 38.80 | Humatrope [LY] |

## ▪ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001



**Authority required**

Short stature and slow growth

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; OR
- Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation of the patient's maturational or constitutional delay status; AND

6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Confirmation that the patient has precocious puberty; AND

7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity above the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of greater than 8 cm per year, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

8. Confirmation that the patient has hypothalamic obesity; AND

9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height at or below the 95$^{th}$ percentile for age on the Turner syndrome growth curve for girls, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height at or below the 25th percentile for age and sex, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ ; AND

6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); OR
- Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist, **AND**
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with no sleep disorders identified; OR
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified which are not of sufficient severity to require treatment; OR
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified for which the patient is currently receiving ameliorative treatment, **AND**
- Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height,

**AND**

- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a chronological age of 18 years or greater.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. A minimum of 6 months of recent growth data (height, weight and waist circumference). The most recent data must not be older than three months; AND

4. The date that skeletal maturity was achieved (if applicable); AND

5. (a) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome; OR

(b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist

6. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months and any sleep disorders identified via polysomnography that required treatment have been addressed; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with 1 repeat allowed)

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**somatropin 5.4 units (1.8 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

| 6318M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 552.02 | 38.80 | Genotropin MiniQuick [PF] |

**somatropin 6 units (2 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

| 6319N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 612.55 | 38.80 | Genotropin MiniQuick [PF] |

**somatropin 4.8 units (1.6 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

| 6317L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 491.48 | 38.80 | Genotropin MiniQuick [PF] |

**somatropin 4.2 units (1.4 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

| 6316K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 430.93 | 38.80 | Genotropin MiniQuick [PF] |

**somatropin 400 microgram injection, syringe [7] (&) inert substance diluent, syringe [7 x 0.25 mL syringes], 1 pack**

| 10902T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 128.23 | 38.80 | Genotropin MiniQuick [PF] |

**SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1**

| 9585L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 223.37 | 38.80 | Genotropin GoQuick [PF] |

**SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1**

| 9586M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 526.07 | 38.80 | Genotropin GoQuick [PF] |

**somatropin 1.8 units (600 microgram) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

| 9628R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 188.78 | 38.80 | Genotropin MiniQuick [PF] |

**somatropin 3 units (1 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

| 6314H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 309.85 | 38.80 | Genotropin MiniQuick [PF] |

**somatropin 2.4 units (800 microgram) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

| 6313G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 249.31 | 38.80 | Genotropin MiniQuick [PF] |

**somatropin 36 units (12 mg) injection [1 cartridge] (&) inert substance diluent [1 mL cartridge], 1 pack**

| 6312F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 526.07 | 38.80 | Genotropin [PF] |

**somatropin 3.6 units (1.2 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

| 6315J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 370.39 | 38.80 | Genotropin MiniQuick [PF] |

## ▪ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.



**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73$m^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months;

OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND

4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must must have had a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine,

clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special**

**Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. Confirmation that the patient has precocious puberty; AND

4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**

- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

9. A bone age result performed within the last 12 months; AND

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. A height measurement from immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**somatropin 12 units (4 mg) injection [1 vial] (&) inert substance diluent [1 vial], 1 pack**

| 10452D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 180.12 | 38.80 | Zomacton [FP] |

**somatropin 30 units (10 mg) injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack**

| 10440L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 439.58 | 38.80 | Zomacton [FP] |

## ▪ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

**Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND

4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must must have had a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. Confirmation that the patient has precocious puberty; AND

4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Recent growth data (height and weight, not older than three months); AND

9. A bone age result performed within the last 12 months; AND

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. A height measurement from immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**somatropin 12 units (4 mg) injection [1 vial] (&) inert substance diluent [1 vial], 1 pack**

10447W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 180.12 | 38.80 | Zomacton [FP] |

**somatropin 30 units (10 mg) injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack**

10455G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 439.58 | 38.80 | Zomacton [FP] |

## ▪ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m$^2$, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m$^2$ prescribers should seek reclassification to the indication short stature and slow growth.

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**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months;

OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND

4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR

- Patient must must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a paediatric endocrinologist; OR
- Must be treated by a medical practitioner in consultation with an endocrinologist specialising in paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.



**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. Confirmation that the patient has precocious puberty; AND

4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

9. A bone age result performed within the last 12 months; AND

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. A height measurement from immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m$^2$ ; AND

5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m$^2$ prescribers should seek reclassification to the indication short stature and slow growth.

**somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge**

| 10507B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 223.37 | 38.80 | Omnitrope Surepal 5 [SZ] |

**somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge**

| 10441M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 439.58 | 38.80 | Omnitrope [SZ] |

**somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge**

| 10506Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 439.58 | 38.80 | Omnitrope Surepal 10 [SZ] |

**somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge**

| 10490D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 655.80 | 38.80 | Omnitrope Surepal 15 [SZ] |

## ▪ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**

- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.



**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m$^2$, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m$^2$ prescribers should seek reclassification to the indication short stature and slow growth.

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**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months;

OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND

4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must must have had a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR

- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**

- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. Confirmation that the patient has precocious puberty; AND

4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine,

clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

9. A bone age result performed within the last 12 months; AND

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. A height measurement from immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73$m^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR

- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m$^2$ ; AND

5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m$^2$ prescribers should seek reclassification to the indication short stature and slow growth.



**somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge**

| 10432C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 223.37 | 38.80 | Norditropin FlexPro [NO] |

**somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge**

| 10469B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 223.37 | 38.80 | Norditropin SimpleXx [NO] |

**somatropin 30 units (10 mg/2 mL) injection, 2 mL cartridge**

| 10478L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 439.58 | 38.80 | NutropinAq [IS] |

**somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge**

| 10439K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 439.58 | 38.80 | Norditropin SimpleXx [NO] |

**somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge**

| 10451C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 439.58 | 38.80 | Norditropin FlexPro [NO] |

**somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge**

| 10449Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 655.80 | 38.80 | Norditropin FlexPro [NO] |

**somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge**

| 10468Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 655.80 | 38.80 | Norditropin SimpleXx [NO] |

## ▪ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**

- Patient must not have been on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.



**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73$m^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months;

OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND

4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.



**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

- Patient must not have an active tumour or evidence of tumour growth or activity.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. Confirmation that the patient has precocious puberty; AND

4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.



**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

9. A bone age result performed within the last 12 months; AND

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. A height measurement from immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73$m^2$, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m$^2$ prescribers should seek reclassification to the indication short stature and slow growth.

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**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m$^2$ ; AND

5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m$^2$ prescribers should seek reclassification to the indication short stature and slow growth.



**somatropin 60 units (20 mg/2.5 mL) injection, 2.5 mL cartridge**

10497L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 872.01 | 38.80 | Saizen [SG] |

**somatropin 18 units (6 mg/1.03 mL) injection, 1.03 mL cartridge**

10462P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 266.61 | 38.80 | Saizen [SG] |

**somatropin 36 units (12 mg/1.5 mL) injection, 1.5 mL cartridge**

10483R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 526.07 | 38.80 | Saizen [SG] |

## ▪ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special**

**Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**

- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m$^2$, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be prepubertal.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m$^2$ prescribers should seek reclassification to the indication short stature and slow growth.

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**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73$m^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months;

OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND

4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must must have had a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic

dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. Confirmation that the patient has precocious puberty; AND

4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

9. A bone age result performed within the last 12 months; AND

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. A height measurement from immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73$m^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73$m^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be prepubertal.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73$m^2$ ; AND

5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73$m^2$ prescribers should seek reclassification to the indication short stature and slow growth.

**somatropin 36 units (12 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack**

| 10487Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 526.07 | 38.80 | Humatrope [LY] |

**somatropin 72 units (24 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack**

| 10476J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 1044.99 | 38.80 | Humatrope [LY] |

**somatropin 18 units (6 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack**

| 10482Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 266.61 | 38.80 | Humatrope [LY] |



## ▪ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73$m^2$, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73$m^2$ ; AND

6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

If a patient receiving treatment under the indication 'short stature associated with chronic renal insufficiency' undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m$^2$ prescribers should seek reclassification to the indication short stature and slow growth.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

**Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND

4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must must have had a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. Confirmation that the patient has precocious puberty; AND

4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Recent growth data (height and weight, not older than three months); AND

9. A bone age result performed within the last 12 months; AND

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature asscіated with Turner syndrome, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. A height measurement from immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73$m^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73$m^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73$m^2$ ; AND

5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m$^2$ prescribers should seek reclassification to the indication short stature and slow growth.

**somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge**

| 10512G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 223.37 | 38.80 | Omnitrope Surepal 5 [SZ] |

**somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge**

| 10481P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 439.58 | 38.80 | Omnitrope [SZ] |

**somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge**

| 10519P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 439.58 | 38.80 | Omnitrope Surepal 10 [SZ] |

**somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge**

| 10485W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 655.80 | 38.80 | Omnitrope Surepal 15 [SZ] |

## ▪ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m$^2$, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be prepubertal.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ ; AND
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

If a patient receiving treatment under the indication 'short stature associated with chronic renal insufficiency' undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m$^2$ prescribers should seek reclassification to the indication short stature and slow growth.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73$m^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND

4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must must have had a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. Confirmation that the patient has precocious puberty; AND

4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Recent growth data (height and weight, not older than three months); AND

9. A bone age result performed within the last 12 months; AND

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. A height measurement from immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73$m^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73$m^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be prepubertal.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ ; AND

5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m$^2$ prescribers should seek reclassification to the indication short stature and slow growth.

**somatropin 36 units (12 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack**

| 10461N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 526.07 | 38.80 | Humatrope [LY] |

**somatropin 72 units (24 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack**

| 10502R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 1044.99 | 38.80 | Humatrope [LY] |

**somatropin 18 units (6 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack**

| 10429X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 266.61 | 38.80 | Humatrope [LY] |

## ▪ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

GH

**Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**

- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**

- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73$m^2$, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73$m^2$ ; AND
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

If a patient receiving treatment under the indication 'short stature associated with chronic renal insufficiency' undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73$m^2$ prescribers should seek reclassification to the indication short stature and slow growth.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73$m^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND

4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must must have had a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. Confirmation that the patient has precocious puberty; AND

4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Recent growth data (height and weight, not older than three months); AND

9. A bone age result performed within the last 12 months; AND

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. A height measurement from immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.



**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73$m^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73$m^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6

months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ ; AND

5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m$^2$ prescribers should seek reclassification to the indication short stature and slow growth.

**somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge**

| 10437H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 223.37 | 38.80 | Norditropin SimpleXx [NO] |

**somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge**

| 10467X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 223.37 | 38.80 | Norditropin FlexPro [NO] |

**somatropin 30 units (10 mg/2 mL) injection, 2 mL cartridge**

| 10438J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 439.58 | 38.80 | NutropinAq [IS] |

**somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge**

| 10448X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 439.58 | 38.80 | Norditropin SimpleXx [NO] |

**somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge**

| 10496K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 439.58 | 38.80 | Norditropin FlexPro [NO] |

**somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge**

| 10470C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 655.80 | 38.80 | Norditropin SimpleXx [NO] |

**somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge**

| 10489C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 655.80 | 38.80 | Norditropin FlexPro [NO] |

## ▪ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

**Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73$m^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND

4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must must have had a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic

dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. Confirmation that the patient has precocious puberty; AND

4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**

- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Recent growth data (height and weight, not older than three months); AND

9. A bone age result performed within the last 12 months; AND

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. A height measurement from immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6

months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73$m^2$, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73$m^2$ ; AND

6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

If a patient receiving treatment under the indication 'short stature associated with chronic renal insufficiency' undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m$^2$ prescribers should seek reclassification to the indication short stature and slow growth.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ ; AND

5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m$^2$ prescribers should seek reclassification to the indication short stature and slow growth.



**somatropin 60 units (20 mg/2.5 mL) injection, 2.5 mL cartridge**

10442N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 872.01 | 38.80 | Saizen [SG] |

**somatropin 18 units (6 mg/1.03 mL) injection, 1.03 mL cartridge**

10458K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 266.61 | 38.80 | Saizen [SG] |

**somatropin 36 units (12 mg/1.5 mL) injection, 1.5 mL cartridge**

10495J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 526.07 | 38.80 | Saizen [SG] |

## ▪ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

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**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73$m^2$, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73$m^2$ ; AND
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

If a patient receiving treatment under the indication 'short stature associated with chronic renal insufficiency' undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73$m^2$ prescribers should seek reclassification to the indication short stature and slow growth.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

**Authority required**

Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and poor body composition due to Prader Willi syndrome category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a current bone age below skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies); OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by a significant medical illness; OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have been re-evaluated via polysomnography for airway obstruction and apnoea during the initial 32 week treatment period and any sleep disorders identified that required treatment must have been addressed, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

**Population criteria:**

- Patient must not have a chronological age of equal to or greater than 18 years.

**Clinical criteria:**

- Patient must not have developed uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height, weight, and waist circumference, not older than three months); AND

4. The date at which skeletal maturity was achieved (if applicable) [Note: A bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity.]; AND

5. Confirmation that during the initial 32 week treatment period, the patient was re-evaluated via polysomnography for airway obstruction and apnoea, and any sleep disorders that were identified have been addressed; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted**.**

**Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73$m^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND

4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must must have had a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of

growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. Confirmation that the patient has precocious puberty; AND

4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic

dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Recent growth data (height and weight, not older than three months); AND

9. A bone age result performed within the last 12 months; AND

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. A height measurement from immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR

- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ ; AND

5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m$^2$ prescribers should seek reclassification to the indication short stature and slow growth.

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**Authority required**

Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and poor body composition due to Prader-Willi syndrome, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a current bone age below skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies) , unless response was affected by an adverse reaction to growth hormone; OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems,

**AND**

- Patient must have diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); OR
- Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist, **AND**
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment and any sleep disorders identified that required treatment must have been addressed; OR
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with no sleep disorders identified; OR
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified which are not of sufficient severity to require treatment; OR
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified for which the patient is currently receiving ameliorative treatment, **AND**
- Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height,

**AND**

- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 18 years or greater.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome, OR

(b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; AND

4. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment, and any sleep disorders identified via the polysomnography that required treatment have been addressed; AND

5. Recent growth data (height and weight, not older than three months); AND

6. The date that skeletal maturity was achieved (if applicable); AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**somatropin 5.4 units (1.8 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

| 10501Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 552.02 | 38.80 | Genotropin MiniQuick [PF] |

**somatropin 6 units (2 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

| 10472E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 612.55 | 38.80 | Genotropin MiniQuick [PF] |

**somatropin 4.8 units (1.6 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

| 10498M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 491.48 | 38.80 | Genotropin MiniQuick [PF] |

**somatropin 4.2 units (1.4 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

| 10434E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 430.93 | 38.80 | Genotropin MiniQuick [PF] |

**somatropin 400 microgram injection, syringe [7] (&) inert substance diluent, syringe [7 x 0.25 mL syringes], 1 pack**

| 10908D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 128.23 | 38.80 | Genotropin MiniQuick [PF] |

**SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1**

| 10435F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 223.37 | 38.80 | Genotropin GoQuick [PF] |

**SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1**

| 10426R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 526.07 | 38.80 | Genotropin GoQuick [PF] |

**somatropin 1.8 units (600 microgram) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

| 10477K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 188.78 | 38.80 | Genotropin MiniQuick [PF] |

**somatropin 3 units (1 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

| 10430Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 309.85 | 38.80 | Genotropin MiniQuick [PF] |

**somatropin 2.4 units (800 microgram) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

| 10463Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 249.31 | 38.80 | Genotropin MiniQuick [PF] |

**somatropin 36 units (12 mg) injection [1 cartridge] (&) inert substance diluent [1 mL cartridge], 1 pack**

| 10444Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 526.07 | 38.80 | Genotropin [PF] |

**somatropin 3.6 units (1.2 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

| 10457J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 370.39 | 38.80 | Genotropin MiniQuick [PF] |

## ▪ SOMATROPIN

**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

GH

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
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Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

- Patient must not have been on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73$m^2$, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73$m^2$ prescribers should seek reclassification to the indication short stature and slow growth.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
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Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and poor body composition due to Prader-Willi syndrome category, **AND**
- Patient must have been re-evaluated via polysomnography for airway obstruction and apnoea during the initial 32 week treatment period and any sleep disorders identified that required treatment must have been addressed, **AND**
- Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must have maintained or improved height percentile for age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must have maintained or improved body mass index SDS for age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR

- Patient must have maintained or improved waist circumference while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must have maintained or improved waist/height ratio (waist circumference in centimetres divided by height in centimetres) while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must have achieved an increase in height percentile with reference to the untreated Prader-Willi syndrome standards for age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must not have been on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must have maintained or improved body mass index while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must have maintained or improved body mass index SDS for age and sex while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must have maintained or improved waist circumference while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must have maintained or improved waist/height ratio (waist circumference in centimetres divided by height in centimetres) while on the maximum dose of 0.04mg/kg/week for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must have maintained or improved weight SDS for age and sex while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

**Population criteria:**

- Patient must not have a chronological age of equal to or greater than 18 years.

**Clinical criteria:**

- Patient must not have developed uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height, weight and waist circumference) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. The date at which skeletal maturity was achieved (if applicable) [Note: A bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity.]; AND

5. Confirmation that during the initial 32 week treatment period, the patient was re-evaluated via polysomnography for airway obstruction and apnoea, and any sleep disorders that were identified have been addressed; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Maintenance is defined as a value within a 5% tolerance (this allows for seasonal and other measurement variations).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826
HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73$m^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months;

OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND

4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must must have had a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1$^{st}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR

- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs

Reply Paid 9826
HOBART TAS 7001

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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HOBART TAS 7001

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**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. Confirmation that the patient has precocious puberty; AND

4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

9. A bone age result performed within the last 12 months; AND

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
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Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. A height measurement from immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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HOBART TAS 7001

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity equal to or less than the 25$^{th}$ percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25$^{th}$ percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73$m^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73$m^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73$m^2$ ; AND

5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73$m^2$ prescribers should seek reclassification to the indication short stature and slow growth.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Continuing treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and poor body composition due to Prader-Willi syndrome, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a current bone age below skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies) , unless response was affected by an adverse reaction to growth hormone; OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems,

**AND**

- Patient must have diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); OR
- Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist, **AND**
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment and any sleep disorders identified that required treatment must have been addressed, **AND**
- Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height,

**AND**

- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 18 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome, OR

(b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; AND

4. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment, and any sleep disorders identified via the polysomnography that required treatment have been addressed; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. The date that skeletal maturity was achieved (if applicable); AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

**somatropin 5.4 units (1.8 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

| 10500P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 552.02 | 38.80 | Genotropin MiniQuick [PF] |

**somatropin 6 units (2 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

| 10428W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 612.55 | 38.80 | Genotropin MiniQuick [PF] |

**somatropin 4.8 units (1.6 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

| 10454F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 491.48 | 38.80 | Genotropin MiniQuick [PF] |

**somatropin 4.2 units (1.4 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

| 10488B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 430.93 | 38.80 | Genotropin MiniQuick [PF] |

**somatropin 400 microgram injection, syringe [7] (&) inert substance diluent, syringe [7 x 0.25 mL syringes], 1 pack**

| 10891F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 128.23 | 38.80 | Genotropin MiniQuick [PF] |

**SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1**

| 10443P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 223.37 | 38.80 | Genotropin GoQuick [PF] |

**SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1**

| 10431B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 526.07 | 38.80 | Genotropin GoQuick [PF] |

**somatropin 1.8 units (600 microgram) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

| 10456H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 188.78 | 38.80 | Genotropin MiniQuick [PF] |

**somatropin 3 units (1 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

| 10480N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 309.85 | 38.80 | Genotropin MiniQuick [PF] |

**somatropin 2.4 units (800 microgram) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

| 10479M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 249.31 | 38.80 | Genotropin MiniQuick [PF] |

**somatropin 36 units (12 mg) injection [1 cartridge] (&) inert substance diluent [1 mL cartridge], 1 pack**

| 10499N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 526.07 | 38.80 | Genotropin [PF] |

**somatropin 3.6 units (1.2 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack**

| 10453E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 370.39 | 38.80 | Genotropin MiniQuick [PF] |

# IVF Treatment Program

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# GENITO URINARY SYSTEM AND SEX HORMONES

## SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

### PROGESTOGENS

*Pregnen (4) derivatives*

#### PROGESTERONE

**Authority required (STREAMLINED)**

***4997***

Assisted Reproductive Technology

**Clinical criteria:**

- The treatment must be for luteal phase support as part of an assisted reproductive technology (ART) treatment cycle for infertile women, **AND**
- Patient must be receiving medical services as described in items 13200 or 13201 of the Medicare Benefits Schedule.

The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.

**progesterone 100 mg pessary, 15**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9608Q | 3 | .. | .. | *156.55 | 38.80 | Oripro [ON] |

**progesterone 100 mg pessary, 21**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10116K | 2 | .. | .. | *104.99 | 38.80 | Endometrin [FP] |

**progesterone 200 mg capsule, 42**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10930G | 1 | .. | .. | 86.68 | 38.80 | Utrogestan [HB] |

**progesterone 200 mg pessary, 15**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9609R | 3 | .. | .. | *171.94 | 38.80 | Oripro [ON] |

#### PROGESTERONE

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***5045***

Assisted Reproductive Technology

**Clinical criteria:**

- The treatment must be for luteal phase support as part of an assisted reproductive technology (ART) treatment cycle for infertile women, **AND**
- Patient must be receiving medical services as described in items 13200 or 13201 of the Medicare Benefits Schedule.

The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.

**progesterone 8% vaginal gel, 15 applications**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 6366C | 2 | .. | .. | *300.59 | 38.80 | Crinone 8% [SG] |

### GONADOTROPINS AND OTHER OVULATION STIMULANTS

*Gonadotropins*

#### CHORIOGONADOTROPIN ALFA

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***5019***

Assisted Reproductive Technology

**Clinical criteria:**

- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**choriogonadotropin alfa 250 microgram/0.5 mL injection, 1 dose**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 6182J | 1 | .. | .. | 63.21 | 38.80 | Ovidrel [SG] |

## ▪ CORIFOLLITROPIN ALFA

**Authority required (STREAMLINED)**

***5009***

Assisted Reproductive Technology

**Clinical criteria:**

- The treatment must be for controlled ovarian stimulation, **AND**
- Patient must have an antral follicle count of 20 or less, **AND**
- Patient must be receiving medical services as described in items 13200, 13201, or 13202 of the Medicare Benefits Schedule, **AND**
- Patient must be undergoing a gonadotrophin releasing antagonist cycle.

**corifollitropin alfa 100 microgram/0.5 mL injection, 0.5 mL syringe**

| 5816D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 412.37 | 38.80 | Elonva [MK] |

**corifollitropin alfa 150 microgram/0.5 mL injection, 0.5 mL syringe**

| 5817E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 672.57 | 38.80 | Elonva [MK] |

## ▪ FOLLITROPIN ALFA

**Authority required (STREAMLINED)**

***5027***

Assisted Reproductive Technology

**Clinical criteria:**

- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**follitropin alfa 900 units (65.52 microgram)/1.5 mL injection, 1.5 mL cartridge**

| 6433N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 5 | .. | .. | *1684.55 | 38.80 | Gonal-f Pen [SG] |

**follitropin alfa 300 units (22 microgram)/0.5 mL injection, 5 x 0.5 mL injection devices**

| 10866X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | .. | .. | *1684.54 | 38.80 | Bemfola [FX] |

**follitropin alfa 450 units (33 microgram)/0.75 mL injection, 5 x 0.75 mL injection devices**

| 10867Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | .. | .. | *2503.24 | 38.80 | Bemfola [FX] |

**follitropin alfa 300 units (21.84 microgram)/0.5 mL injection, 0.5 mL cartridge**

| 6431L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *234.21 | 38.80 | Gonal-f Pen [SG] |

**follitropin alfa 225 units (16.5 microgram)/0.375 mL injection, 5 x 0.375 mL injection devices**

| 10872F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | .. | .. | *1275.19 | 38.80 | Bemfola [FX] |

**follitropin alfa 75 units (5.5 microgram)/0.125 mL injection, 5 x 0.125 mL injection devices**

| 10861P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | .. | .. | *432.88 | 38.80 | Bemfola [FX] |

**follitropin alfa 150 units (11 microgram)/0.25 mL injection, 5 x 0.25 mL injection devices**

| 10873G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | .. | .. | *858.61 | 38.80 | Bemfola [FX] |

**follitropin alfa 450 units (32.76 microgram)/0.75 mL injection, 0.75 mL cartridge**

| 6432M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *347.73 | 38.80 | Gonal-f Pen [SG] |

## ▪ FOLLITROPIN ALFA + LUTROPIN ALFA

**Authority required (STREAMLINED)**

***5250***

Stimulation of follicular development

**Clinical criteria:**

- Patient must have severe LH deficiency, **AND**

- Patient must be considered appropriate for treatment with the combination product after titration of FSH and LH after at least one cycle of treatment, **AND**
- Patient must be receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**follitropin alfa 150 units + lutropin alfa 75 units [1 vial] (&) inert substance diluent [1 vial], 1 pack**

10491E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 14 | .. | .. | *2186.95 | 38.80 | Pergoveris [SG] |

## ▪ FOLLITROPIN BETA

**Authority required (STREAMLINED)**

***5027***

Assisted Reproductive Technology

**Clinical criteria:**

- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge**

6335K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *303.55 | 38.80 | Puregon 300 IU/0.36 mL [MK] |

**follitropin beta 900 units/1.08 mL injection, 1.08 mL cartridge**

6464F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | .. | .. | *2114.10 | 38.80 | Puregon 900 IU/1.08 mL [MK] |

**follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge**

6336L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | .. | .. | *1159.47 | 38.80 | Puregon 600 IU/0.72 mL [MK] |

## ▪ HUMAN CHORIONIC GONADOTROPHIN

**Authority required (STREAMLINED)**

***6991***

Assisted Reproductive Technology

**Clinical criteria:**

- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**human chorionic gonadotrophin 5000 units injection [1 vial] (&) inert substance diluent [1 mL vial], 1 pack**

11156E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *27.33 | 28.54 | Pregnyl [MK] |

**human chorionic gonadotrophin 1500 units injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack**

11154C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 41.89 | 38.80 | Pregnyl [MK] |

## ▪ HUMAN MENOPAUSAL GONADOTROPHIN

**Authority required (STREAMLINED)**

***5027***

Assisted Reproductive Technology

**Clinical criteria:**

- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**human menopausal gonadotrophin 600 units injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack**

2036E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | .. | .. | *835.78 | 38.80 | Menopur 600 [FP] |

**human menopausal gonadotrophin 1200 units injection [1 vial] (&) inert substance diluent [2 x 1 mL syringes], 1 pack**

2038G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | .. | .. | *2171.87 | 38.80 | Menopur 1200 [FP] |

## ▪ LUTROPIN ALFA

**Authority required (STREAMLINED)**

***5251***

Stimulation of follicular development

**Clinical criteria:**

- Patient must have severe LH deficiency, **AND**
- Patient must be receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**lutropin alfa 75 units injection [1 vial] (&) inert substance diluent [1 mL vial], 1 pack**

| 10465T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 14 | .. | .. | *1422.69 | 38.80 | Luveris [SG] |

# SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

## PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

### HYPOTHALAMIC HORMONES

*Gonadotropin-releasing hormones*

### NAFARELIN

**Authority required (STREAMLINED)**

***5046***

Assisted Reproductive Technology

**Clinical criteria:**

- The treatment must be for prevention of premature luteinisation and ovulation, **AND**
- Patient must be undergoing controlled ovarian stimulation, **AND**
- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**nafarelin 200 microgram/actuation nasal spray, 60 actuations**

| 5815C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *227.63 | 38.80 | Synarel [PF] |

*Anti-gonadotropin-releasing hormones*

### CETRORELIX

**Authority required (STREAMLINED)**

***5046***

Assisted Reproductive Technology

**Clinical criteria:**

- The treatment must be for prevention of premature luteinisation and ovulation, **AND**
- Patient must be undergoing controlled ovarian stimulation, **AND**
- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.



**cetrorelix 250 microgram injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack**

| 9599F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 10 | .. | .. | *462.45 | 38.80 | Cetrotide [SG] |

### GANIRELIX

**Authority required (STREAMLINED)**

***5046***

Assisted Reproductive Technology

**Clinical criteria:**

- The treatment must be for prevention of premature luteinisation and ovulation, **AND**
- Patient must be undergoing controlled ovarian stimulation, **AND**
- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**ganirelix 250 microgram/0.5 mL injection, 0.5 mL syringe**

| 9583J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 10 | .. | .. | *462.45 | 38.80 | Orgalutran [MK] |

**ganirelix 250 microgram/0.5 mL injection, 5 x 0.5 mL syringes**

| 9584K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *462.47 | 38.80 | Orgalutran [MK] |

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

## ENDOCRINE THERAPY

### HORMONES AND RELATED AGENTS

*Gonadotropin releasing hormone analogues*

## ▪ TRIPTORELIN

**Authority required (STREAMLINED)**

***5046***

Assisted Reproductive Technology

**Clinical criteria:**

- The treatment must be for prevention of premature luteinisation and ovulation, **AND**
- Patient must be undergoing controlled ovarian stimulation, **AND**
- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**triptorelin acetate 100 microgram/mL injection, 7 x 1 mL syringes**

10907C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | .. | .. | *216.59 | 38.80 | Decapeptyl [FP] |

# Opiate Dependence Treatment Program

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# NERVOUS SYSTEM

## OTHER NERVOUS SYSTEM DRUGS

### DRUGS USED IN ADDICTIVE DISORDERS

*Drugs used in opioid dependence*

### BUPRENORPHINE

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Opiate dependence

Treatment Phase: Maintenance and detoxification (withdrawal)

**Clinical criteria:**

- The treatment must be within a framework of medical, social and psychological treatment.

**buprenorphine 2 mg sublingual tablet, 7**

6308B NP

| Max.Qty Packs | Price ex manufacturer $ | Brand Name and Manufacturer |
|---|---|---|
| 1 | 9.98 | Subutex [IR] |

**buprenorphine 8 mg tablet, 7**

6309C NP

| Max.Qty Packs | Price ex manufacturer $ | Brand Name and Manufacturer |
|---|---|---|
| 1 | 28.60 | Subutex [IR] |

**buprenorphine 400 microgram sublingual tablet, 7**

6307Y NP

| Max.Qty Packs | Price ex manufacturer $ | Brand Name and Manufacturer |
|---|---|---|
| 1 | 5.85 | Subutex [IR] |

### BUPRENORPHINE + NALOXONE

**Note** Buprenorphine with naloxone soluble film and buprenorphine with naloxone sublingual tablet do not meet all the criteria for bioequivalence. Patients being switched between sublingual tablets and soluble films may therefore require a dosage adjustment.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Opiate dependence

**Clinical criteria:**

- The treatment must be within a framework of medical, social and psychological treatment.

**buprenorphine 2 mg + naloxone 500 microgram sublingual film, 28**

9749D NP

| Max.Qty Packs | Price ex manufacturer $ | Brand Name and Manufacturer |
|---|---|---|
| 1 | 46.20 | Suboxone Film 2/0.5 [IR] |

**buprenorphine 8 mg + naloxone 2 mg sublingual film, 28**

9750E NP

| Max.Qty Packs | Price ex manufacturer $ | Brand Name and Manufacturer |
|---|---|---|
| 1 | 132.44 | Suboxone Film 8/2 [IR] |

### METHADONE

**Caution** The risk of drug dependence is high.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Opiate dependence

ODT

**methadone hydrochloride 5 mg/mL oral liquid, 1 L**

6172W

NP

| Max.Qty Packs | Price ex manufacturer $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|
| 1 | 33.20 | [a] Aspen Methadone Syrup [QA] | [a] Biodone Forte [MW] |

**methadone hydrochloride 5 mg/mL oral liquid, 200 mL**

6171T

NP

| Max.Qty Packs | Price ex manufacturer $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|
| 1 | 7.91 | [a] Aspen Methadone Syrup [QA] | [a] Biodone Forte [MW] |

# Repatriation Pharmaceutical Benefits Scheme

## BENEFICIARIES' ENTITLEMENT CARDS AND ELIGIBILITY FOR REPATRIATION PHARMACEUTICAL BENEFITS

**Gold card**
This card is issued to those veterans of Australia's defence force, their widows/widowers and dependants entitled to treatment for all medical conditions.




**White card**
A White Card is issued to Australian veterans or mariners under the Veterans' Entitlements Act 1986 with:

- an accepted war or service-caused injury or disease;
- malignant cancer (neoplasia) whether war-caused or not;
- pulmonary tuberculosis whether war-caused or not;
- post-traumatic stress disorder whether war-caused or not; or
- anxiety and/or depression whether war-caused or not.




**Orange card**
Orange Repatriation pharmaceutical benefits cards are issued to Commonwealth and allied veterans and mariners who:

- have qualifying service from World War I or II and
- are aged 70 or over and
- have been resident in Australia for 10 years or more.




For more information go to the Department of Veterans' Affairs website:
http://www.dva.gov.au

# RPBS Explanatory Notes
## Introduction

### *The Australian Repatriation System*

- The Australian Repatriation system is based primarily on the principle of compensation to veterans and eligible dependants for injury or death related to war service. In certain cases, treatment is also provided for accepted injuries or conditions that are not service-related or have occurred as a result of other than war service.
- Through the *Veterans' Entitlements Act 1986* the Department of Veterans' Affairs provides programs of compensation, income support and treatment for eligible veterans and their dependants. One of the defined benefits for eligible veterans is the Repatriation Pharmaceutical Benefits Scheme. This range of medications and dressings is more comprehensive than is available through the Pharmaceutical Benefits Scheme.

## RPBS prescribing provisions

- Unless otherwise stated, Repatriation Pharmaceutical Benefits Scheme (RPBS) prescriptions must conform with the requirements of Pharmaceutical Benefits Scheme (PBS) prescriptions, as detailed in Section 1 – Explanatory Notes in the *Schedule of Pharmaceutical Benefits* book. The prescriber shall ensure that a prescription contains the following details:
  - the category of benefit, i.e., RPBS, by placing a cross in the relevant box;
  - the patient's full name and address;
  - the prescription date;
  - the DVA file number of the patient as evidence of entitlement;
  - in the case of authority prescriptions, the Authority approval number or the four digit streamlined authority code;
  - the item, form, strength, quantity and directions;
  - the number of repeats, if applicable;
  - indicate when brand substitution is not permitted; and
  - the name, signature, the prescriber number and address of the prescriber.

### *Prior Approval Arrangements*

- The prior approval of the Department is required to prescribe the following:
  - 'Authority required' items (excluding 'Authority required (STREAMLINED)' items) listed in either the PBS or RPBS Schedule;
  - increased quantities and/or repeats of items listed in either the PBS or RPBS Schedule;
  - items listed under section 100 of the *National Health Act 1953*; and
  - other items not listed in either Schedule (non-Schedule items).
- The above items are to be prescribed on the common PBS/RPBS authority prescription form in accordance with the directions stated in the Explanatory Notes in the *Schedule of Pharmaceutical Benefits* (See also information regarding dental prescribing and prescribing by optometrists under the RPBS in these Notes.)
- All Authority required prescriptions and requests for non-Schedule items must receive prior approval from the Department. This can be achieved by either:
  - using the Department's national free call number 1800 552 580; or
  - by mailing the written authority prescription to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) at the reply paid address shown at the end of these RPBS Explanatory Notes.

Prior approval is not required from DVA to prescribe an Authority required (STREAMLINED) item (except where increased quantities and/or repeats are required). Instead the authority prescription form must include a four digit streamlined authority code.

- Some requests for prior approval (including some non-Schedule items) need to be referred by VAPAC to the Repatriation Pharmaceutical Reference Committee for consideration. In such cases a VAPAC pharmacist will advise the prescriber to submit a request in writing that provides the following information:
  - A current clinical report on the patient's condition (such as age, co-morbidities, renal, liver failure) and clinical reports including pathology, biochemistry, diagnostic and other investigations if appropriate.
  - Details of past and current therapy for the condition. Include details of PBS, RPBS and non-Schedule items utilised, and the results of those therapies.
  - Details of the proposed treatment regimen. Include intended dose and duration of treatment and objective measures of response.
  - When the proposed use of the item is outside the TGA-approved indications for use in Australia, provide copies of articles from peer reviewed publications supporting the proposed treatment.
  - Signed, informed patient consent where the item is to be used for a non-TGA-approved indication.
  - For items without Australian marketing approval, a copy of the TGA Special Access Scheme approval to prescribe the drug.
- Requests for prior approval to prescribe a non-Schedule (PBS or RPBS) item that is of the same therapeutic class (ATC level 3) as an item that is listed on the Schedule, will not be approved unless unequivocal clinical evidence is presented to demonstrate that the requested item is essential for effective treatment of the nominated patient.
- A pharmacist should not supply an item prescribed on an RPBS Authority Prescription Form unless the form has been approved and stamped by VAPAC, or has been endorsed by the prescriber with a telephone Authority approval number provided by VAPAC. Medicare Australia will not accept RPBS Authority prescriptions that have not been approved by the Department of Veterans' Affairs for payment.

### *Palliative Care Drugs*

- The following medications may be available, or made available in increased quantities or doses under prior approval arrangements for use only in the palliative care of terminal disease:
  - clonazepam
  - cyclizine
  - dexamethasone

- o disodium pamidronate
- o fentanyl
- o glycopyrrolate
- o hyoscine butylbromide
- o hyoscine hydrobromide
- o ketamine
- o midazolam
- o octreotide

- For further information telephone VAPAC on 1800 552 580.

### *Dental Prescribing*

- Under Department of Veterans' Affairs arrangements, financial responsibility for pharmaceutical benefits prescribed by a Local Dental Officer (LDO) is limited to treatment to which holders of the following cards are entitled: Where possible the LDO shall prescribe in accordance with the provisions governing dental prescribing under the Pharmaceutical Benefits Scheme (PBS).
  - o a Gold Repatriation Health Card – For All Conditions; or
  - o a White Repatriation Health Card – For Specific Conditions; or
  - o an Orange Repatriation Pharmaceutical Benefits Card.
- Prescriptions for PBS Dental Schedule items for Gold, White and Orange Card holders are to be dispensed at the PBS concessional rate. Claims for payment by the dispensing pharmacist are to be included with other Repatriation prescriptions. The card holder is required to meet the cost of any applicable brand premium.
- When a non-PBS Dental Schedule item is prescribed for an eligible card holder, the LDO's private prescription form should be used. The dispensing pharmacist may charge the patient the full cost of the prescription. The patient may claim a refund for the full cost of a non-Schedule item from the Department if an itemised receipt (not a cash register receipt) and a copy of the prescription are provided.

### *Prescribing by optometrists*

- Optometrists approved as 'PBS prescribers' may write RPBS prescriptions as outlined in Section 1 for medicines listed in Section 2 of the PBS Schedule as pharmaceutical benefits for optometrical use.
- Medicines in the optometrist list include non-Authority and Authority required items. Procedures for obtaining VAPAC approval to prescribe 'Authority required' optometrist items or increased quantities and/or repeats of optometrist items under the RPBS are the same as indicated under prior approval arrangements above.
- The list of medicines for prescribing by optometrists under the RPBS is the same as applies under the PBS. There are no optometrist listings in the RPBS Schedule for prescribing for veterans only. There is no provision for optometrist prescribers to request approval to prescribe items that are not included in the PBS optometrist list (non-Schedule items).
- Optometrist PBS/RPBS prescription forms are for use for prescribing non-Authority or Authority required optometrist items under the RPBS with one item per form only.

## Provisions governing pricing and payment for RPBS benefits

### *Introduction*

- Unless otherwise stated, the pricing and payment principles and arrangements for approved pharmacists supplying pharmaceutical benefits under the RPBS will be the same as those arrangements applying under the PBS.
- Where a pharmaceutical benefit that is not listed on the PBS or RPBS Schedule is dispensed on an RPBS Authority prescription, a pharmacist will price the benefit and enter the serial number, prescription identifying number and price on the sticker or stamp imprint affixed to the prescription.

### *Pricing of Schedule Items*

- Items supplied under the RPBS from the PBS Schedule, both ready-prepared and extemporaneously-prepared, will be paid on the same basis as benefits supplied under the PBS. Items supplied under the RPBS from the Repatriation Schedule, including wound dressings, will be paid on the basis of the price as given in the Repatriation Pharmaceutical Benefits section (Section 1 – RPBS Schedule, Drugs, Medicines and Dressings) of the *Schedule of Pharmaceutical Benefits*.

### *Pricing of Non-Schedule Ready Prepared Items*

- Non-Schedule ready-prepared items are to be priced on the basis of the invoiced, GST-exclusive wholesale price to pharmacists plus the appropriate PBS mark-up and the PBS dispensing fee. Where the item price to pharmacists is greater than $100.00, a copy of the invoice pertaining to the supply of that item is to be submitted together with the appropriate copy of the authority prescription as part of the claim for payment.

### *Pricing of Non-Schedule Extemporaneously Prepared Items*

- When an ingredient drug is not listed in the PBS Drug Tariff, the recovery price will be based on the invoiced wholesale price to pharmacists, increased by a mark-up of 100%, calculated in accordance with the directions contained in the pricing instructions for pricing of PBS extemporaneously-prepared benefits in this Schedule. The price paid by the pharmacist for the commercial pack from which the ingredient is used shall be endorsed on the prescription form.

### *Miscellaneous Pricing Rules*

- The price to pharmacists used as the basis of pricing will be the invoiced, GST-exclusive price from the wholesaler.
- If multiple quantities of a manufacturer's original pack are supplied, the PBS mark-up is applied to the price to pharmacist of each pack and then totalled. The PBS dispensing fee, and the PBS dangerous drug fee if applicable, are then added to the total of the marked-up prices.
- When the quantity prescribed corresponds with the quantity of a manufacturer's original pack, in no circumstances will the price payable for one pack exceed that payable for multiples or combinations of packs to supply the quantity prescribed.

- The list of ingredient drugs and prices included in the PBS Drug Tariff are common to both the PBS and RPBS. Certain restrictions apply regarding the prescribing and dispensing of some of these ingredient drugs as pharmaceutical benefits, e.g., use as additive only.
- For items prescribed generically, including non-Schedule and wound dressings, the pharmacist should indicate on the prescription the quantity and brand supplied. If prescriptions are not endorsed, the Department will pay the lowest priced acceptable product available.

## General

### *Packaging Material, Postage or Freight*

- Payment to a pharmacist for the costs of packaging materials, postage or freight required to supply a pharmaceutical benefit is to be paid by the patient, who may then claim reimbursement from the Department through the provision of a pharmacists itemised receipt.

### *Payment for Items Supplied at Short Intervals*

- For all items dispensed at specific short intervals of time, the Department will pay a separate PBS dispensing fee for each occasion that the drug is supplied and which is acknowledged on receipt by the patient or agent.
- The price payable on the items supplied will be based on the individual dose quantity supplied. Where applicable, a PBS dangerous drug fee and a minimum container charge will be payable for each supply.

### *Receipts for Patient Charges*

- Where a charge is paid by a patient in any of the circumstances of paragraphs 13 or 24, the pharmacist is required to provide a printed receipt to the patient with the details of the items or services provided, the amount paid, date of supply and the patients name and address. The patient may apply for reimbursement from the Department.

### *Special Patient Contributions*

- The Special Patient Contribution for items listed as Special Pharmaceutical Benefits in the PBS Schedule is not payable by veterans entitled to pharmaceutical benefits under the RPBS. Eligible veterans receiving Special Pharmaceutical Benefits under the RPBS are required to pay only the concessional patient contribution and any applicable brand premium. If a Safety Net Entitlement card is held, the veteran should receive a Special Pharmaceutical Benefit free of charge, subject to any brand premium applicable. Medicare Australia will reimburse the dispensing pharmacist the total dispensed price, less the concessional patient contribution and/or brand premium if applicable.

### *Therapeutic Group Premiums — Authority Processing*

- Items attracting a therapeutic group premium are dual listed. Dispensing pharmacists are therefore required to select the appropriate code for those items that are dual listed as authority and non-authority items, in order to correctly charge the patient and claim from Medicare Australia. Those authority prescriptions that grant exemption from a therapeutic group premium will have the letters 'TPX' at the beginning of the telephone Authority approval number, or, in the case of a written approval, will be stamped with the words "This prescription does not attract a therapeutic group premium".

# Contact the Department of Veterans' Affairs

**Authority Prescription Applications**

Applications for authority to prescribe under the Repatriation Pharmaceutical Benefits Scheme (RPBS) should be sent to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) using the free postal service:

REPLY PAID 9998
VAPAC (Veterans' Affairs Pharmaceutical Advisory Centre)
Department of Veterens' Affairs
GPO Box 9998
BRISBANE QLD 4001

**For RPBS enquiries and telephone approvals 24 hours a day the Freecall number is: 1800 552 580**
**Departmental pharmacists answer applications for prior approval for non-Schedule items and Authority application calls.**

# Wound Assessment and Dressing Identification

It is essential to define the aetiology of the wound before selecting a dressing. Recommendations are based on wound type, colour of wound base, depth of wound, and amount of exudate.
This wound chart adheres to the MOIST WOUND concept of healing and wound dressings are described below as ABSORBING or MOISTURE DONATING.
Most wound healing products are designed to remain in situ for several days, with the exception of those for infected wounds which should be changed daily. The quantities and repeats listed in the Repatriation Schedule are considered to be adequate to manage the treatment of a wound for two weeks to one month, when an assessment of the wound's healing process should be undertaken.

**DRESSINGS**

**Pink Epithelialising Wound**

Aim: To protect and promote epithelialisation. Epithelialising wounds normally are superficial and only produce a light exudate.

| | | |
|---|---|---|
| (A) Covering | o Film;<br>o Film Island | o Gauze—Paraffin;<br>o Non-adherent |
| (B) Absorbing | o Foam (Light Exudate);<br>o Hydroactive (Superficial Wound—Light Exudate) | o Hydrocolloid (Superficial Wound—Light Exudate) |

**Red Granulating Wound**

Aims: (1) to protect the granulating tissue; (2) to encourage epithelialisation; (3) to absorb excess exudate.

| LIGHT EXUDATE: | Superficial | Cavity |
|---|---|---|
| (A) Absorbing | o Foam (Light Exudate);<br>o Hydroactive (Superficial Wound—Light Exudate);<br>o Hydrocolloid (Superficial Wound—Light Exudate) | o Hydrocolloid (Cavity Wound) |
| (B) Moisture donating | o Hydrogel—Amorphous;<br>o Hydrogel—Sheet | o Hydrogel—Amorphous |
| HIGH EXUDATE: | Superficial | Cavity |
| (A) Absorbing | o Alginate (Superficial Wound);<br>o Foam—Heavy Exudate;<br>o Hydroactive (Superficial Wound—Moderate Exudate);<br>o Hydrocolloid (Superficial Wound—Moderate/High Exudate) | o Alginate (Cavity Wound);<br>o Foam—Moderate Exudate (see “cavity conforming” product);<br>o Hydroactive (Cavity Wound);<br>o Hydrocolloid (Cavity Wound) |
| (B) Moisture donating | NOT APPROPRIATE | |

**Yellow Sloughy Wound**

Aims: (1) to remove slough; (2) to encourage granulation; (3) to absorb excess exudate.

| LIGHT EXUDATE: | Superficial | Cavity |
|---|---|---|
| (A) Absorbing | o Cadexomer Iodine;<br>o Foam—Light Exudate;<br>o Foam with Charcoal;<br>o Hydroactive (Superficial Wound—Moderate Exudate);<br>o Hydrocolloid (Superficial Wound—Moderate Exudate) | o Cadexomer Iodine;<br>o Hydrocolloid (Cavity Wound) |
| (B) Moisture Donating | o Hydrogel—Amorphous;<br>o Hydrogel—Sheet | o Hydrogel—Amorphous |
| HIGH EXUDATE: | Superficial | Cavity |
| (A) Absorbing | o Alginate (Superficial Wound);<br>o Cadexomer Iodine;<br>o Foam—Heavy Exudate;<br>o Hydroactive (Superficial Wound—Moderate/High Exudate);<br>o Hydrocolloid (Superficial Wound—Moderate/High Exudate) | o Alginate (Cavity Wound);<br>o Cadexomer Iodine;<br>o Hydrocolloid (Cavity Wound) |
| (B) Moisture donating | NOT APPROPRIATE | |

**Black Necrotic Wound**
Aims: To remove eschar by — (1) sharp debridement, e.g., scissor/scalpel and/or (2) rehydration and autolytic debridement. (These wounds usually produce a LIGHT EXUDATE.)

| DRY / LIGHT EXUDATE: | Superficial | Cavity |
|---|---|---|
| (A) Absorbing | o Hydroactive (Superficial Wound—Light Exudate);<br>o Hydrocolloid (Superficial Wound—Light/Moderate Exudate) | o Hydrocolloid (Cavity Wound) |
| (B) Moisture donating | o Hydrogel—Amorphous;<br>o Hydrogel—Sheet | o Hydrogel—Amorphous;<br>o Hydrogel—Sheet |

**Infected Wounds**
Aims: (1) to clear the infection with systemic antibiotics; (2) to absorb excess exudate; (3) to remove slough if present; (4) to decrease bacterial burden - by applying a Silver dressing or Cadexomer Iodine dressing.

**Malodorous Wounds**
Aims: (1) to clear infection if present; (2) to remove slough if present; (3) to clear colonising odour-producing bacteria **in** slough — by applying metronidazole gel, a Silver dressing or a Cadexomer Iodine dressing; (4) to absorb excess exudate.
Products: Activated Charcoal; Alginate with Charcoal; Foam with Charcoal; Silver dressing; Cadexomer Iodine dressing.

**Minor Skin Trauma**
Aims: (1) to stop bleeding; (2) to prevent infection; (3) to minimise the surface defect; (4) to promote epithelialisation.

# Ordering Products

**Ordering Coloplast Products**
Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**Ordering Hartmann Products**
Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

**Ordering Molnlycke Healthcare Products**
Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

**Ordering Smith & Nephew Products**
Smith & Nephew products are distributed via the three major wholesalers, API, SIGMA & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

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ALL OTHER NON-THERAPEUTIC PRODUCTS .... 1630

RPBS

# ALIMENTARY TRACT AND METABOLISM

## STOMATOLOGICAL PREPARATIONS

### STOMATOLOGICAL PREPARATIONS

*Antiinfectives and antiseptics for local oral treatment*

#### CHLORHEXIDINE

**chlorhexidine gluconate 0.2% mouthwash, 300 mL**

| 4204G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 18.79 | 6.30 | Savacol Mouth and Throat Rinse [OM] |

**chlorhexidine gluconate 0.2% mouthwash, 250 mL**

| 4161B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 15.85 | 6.30 | Plaqacide [OB] |

#### NYSTATIN

**nystatin 100 000 units/mL oral liquid, 24 mL**

| 10854G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 17.57 | 6.30 | [a] Pharmacy Action Nystatin Oral Drops [GQ] |
| | | | .. | 18.81 | 6.30 | [a] Mycostatin Oral Drops [QA] |

## DRUGS FOR ACID RELATED DISORDERS

### ANTACIDS

*Calcium compounds*

#### CALCIUM CARBONATE + GLYCINE

**Note** For patients with chronic renal failure.

**calcium carbonate 420 mg + glycine 180 mg chewable tablet, 100**

| 4055K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *25.67 | 6.30 | Titralac [MM] |

*Combinations and complexes of aluminium, calcium and magnesium compounds*

#### ALUMINIUM HYDROXIDE WITH MAGNESIUM HYDROXIDE AND SIMETHICONE

**ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE and SIMETHICONE Oral suspension 400 mg-400 mg-30 mg per 5 mL, 500 mL, 1**

| 4118R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *25.19 | 6.30 | Mylanta Double Strength [JT] |

## DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

### DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

*Synthetic anticholinergics, esters with tertiary amino group*

#### MEBEVERINE

**mebeverine hydrochloride 135 mg tablet, 90**

| 4328T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 28.91 | 6.30 | [a] Colese [AF] |
| | | | .. | 33.41 | 6.30 | [a] Colofac [GO] |

### BELLADONNA AND DERIVATIVES, PLAIN

*Belladonna alkaloids, semisynthetic, quaternary ammonium compounds*

#### HYOSCINE BUTYLBROMIDE

**hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules**

| 4279F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 25.79 | 6.30 | Buscopan [VZ] |

RPBS

# DRUGS FOR CONSTIPATION

## DRUGS FOR CONSTIPATION

*Softeners, emollients*

### DOCUSATE

**docusate sodium 50 mg tablet, 100**

| 4200C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 17.95 | 6.30 | Coloxyl 50 [FM] |

*Contact laxatives*

### BISACODYL

**bisacodyl 10 mg suppository, 12**

| 10580W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 4 | .. | *21.43 | 6.30 | Petrus Bisacodyl Suppositories [PP] |

**bisacodyl 10 mg suppository, 10**

| 10578R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 5 | .. | *23.71 | 6.30 | [a] Petrus Bisacodyl Suppositories [PP] |
| | | | .. | *25.00 | 6.30 | [a] Dulcolax [VZ] |

### DOCUSATE + SENNOSIDE B

**docusate sodium 50 mg + sennoside B 8 mg tablet, 90**

| 10177P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 16.93 | 6.30 | Pharmacy Action Laxative with Senna [GQ] |

**docusate sodium 50 mg + sennoside B 8 mg tablet, 100**

| 4028B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 18.04 | 6.30 | Soflax [EA] |

### DOCUSATE + SENNOSIDES

**docusate sodium 50 mg + sennosides 11.27 mg tablet, 90**

| 4198Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 16.97 | 6.30 | [a] Chemists' Own Laxative with Senna [RW] | [a] Colaxsen [QA] |
| | | | | | | [a] Co-Senna [PP] | |
| | | | .. | 20.02 | 6.30 | [a] Coloxyl with Senna [FM] | |

### SENNOSIDE B

**sennoside B 7.5 mg tablet, 100**

| 4455L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 16.46 | 6.30 | [a] Senna-Gen [PP] |
| | | | .. | 17.56 | 6.30 | [a] Senokot [RC] |

*Bulk-forming laxatives*

### DRY PSYLLIUM HUSK

**dry psyllium husk 3.5 g powder for oral liquid, 30 sachets**

| 4285M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 20.85 | 6.30 | Fybogel [RC] |

### PSYLLIUM HUSK POWDER

**PSYLLIUM HYDROPHILIC MUCILLOID Oral powder (orange-flavoured, sugar-free) 283 g, 1**

| 4419N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 24.35 | 6.30 | Metamucil Orange Smooth [PY] |

**PSYLLIUM HYDROPHILIC MUCILLOID Oral powder (non-flavoured) 336 g, 1**

| 4422R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 21.18 | 6.30 | Fibre Health Natural Granular [PP] |

RPBS

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | .. | 24.35 | 6.30 | Metamucil Natural Granular [PY] |

### ▪ RHAMNUS FRANGULA + STERCULIA

**rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g**

| 4558X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 27.57 | 6.30 | Normacol Plus [NE] |

*Enemas*

### ▪ SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM

**sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 4 x 5 mL**

| 4462W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 16.03 | 6.30 | Micolette [AE] |

*Other drugs for constipation*

### ▪ GLYCEROL

**glycerol 1.4 g suppository, 12**

| 10596Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 5 | .. | *23.32 | 6.30 | Petrus Pharmaceuticals Pty Ltd [PP] |

**glycerol 700 mg suppository, 12**

| 10586E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 5 | .. | *22.96 | 6.30 | Petrus Pharmaceuticals Pty Ltd [PP] |

**glycerol 2.8 g suppository, 12**

| 4246L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 5 | .. | *23.80 | 6.30 | Petrus Pharmaceuticals Pty Ltd [PP] |

## ▪ ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS

### ELECTROLYTES WITH CARBOHYDRATES

*Oral rehydration salt formulations*

### ▪ SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRIC ACID

**sodium chloride 470 mg + potassium chloride 300 mg + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets**

| 10574M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 15.90 | 6.30 | restore O.R.S. [EA] |

### ANTIPROPULSIVES

*Antipropulsives*

### ▪ LOPERAMIDE

**loperamide hydrochloride 2 mg capsule, 12**

| 10592L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 12.58 | 6.30 | Gastrex [CR] |

**loperamide hydrochloride 2 mg capsule, 20**

| 11135C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 12.58 | 6.30 | Pharmacy Action Diarrhoea Relief [GQ] |

## ▪ ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS

### ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS

*Peripherally acting antiobesity products*

### ▪ ORLISTAT

**Note** The patient should be ideally enrolled in an exercise program and be receiving supplemental vitamins.

**Authority required**

Obesity

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a Body Mass Index (BMI) greater than or equal to 35 with no known co-morbidities; OR
- Patient must have a BMI greater than or equal to 30 with 1 or more of the following co-morbidities;(i) diabetes;(ii) ischaemic heart disease;(iii) psychiatric conditions;(iv) hypertension, **AND**
- Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available), **AND**
- The treatment must not exceed 12 months in total from initial application, **AND**
- Patient must not receive more than 1 continuous treatment in a lifetime.

The prescriber must provide the patient's initial body weight and BMI at the time of application.

**Authority required**

Obesity

Treatment Phase: Continuing treatment (3 to 6 months following commencement)

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have reduced their inital body weight by 2.5 kg or 2.5% (whichever is the lesser) during the period 3 to 6 months following commencement of treatment with this drug, **AND**
- The treatment must not exceed 12 months in total from initial application, **AND**
- Patient must not receive more than 1 continuous treatment in a lifetime, **AND**
- Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available).

**Authority required**

Obesity

Treatment Phase: Continuing treatment (6 to 12 months following commencement)

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have reduced their inital body weight by 5 kg or 5% (whichever is the lesser) during the period 6 to 12 months following commencement of treatment with this drug, **AND**
- The treatment must not exceed 12 months in total from initial application, **AND**
- Patient must not receive more than 1 continuous treatment in a lifetime, **AND**
- Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available).

**orlistat 120 mg capsule, 84**

4570M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 132.67 | 6.30 | Xenical [RO] |

# VITAMINS

## VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12

*Vitamin B1, plain*

### THIAMINE

**thiamine hydrochloride 100 mg tablet, 100**

4043T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 14.98 | 6.30 | Betavit [PP] |

## VITAMIN B-COMPLEX, INCL. COMBINATIONS

*Vitamin B-complex, plain*

### FERRIC PYROPHOSPHATE + THIAMINE + PYRIDOXINE + CYANOCOBALAMIN + LYSINE

**cyanocobalamin 25 microgram/10 mL + iron (as ferric pyrophosphate) 10 mg/10 mL + lysine hydrochloride 300 mg/10 mL + pyridoxine hydrochloride 5 mg/10 mL + thiamine hydrochloride 10 mg/10 mL oral liquid, 200 mL**

4493L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 17.11 | 6.30 | Accomin Adult Tonic [PF] |

# MINERAL SUPPLEMENTS

## CALCIUM

*Calcium*

### CALCIUM

**Restricted benefit**

Hyperphosphataemia

**Clinical criteria:**

RPBS

- The condition must be associated with chronic renal failure.

**CALCIUM Tablet (chewable) 500 mg (as carbonate), 60**

| 4094L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 4 | 1 | .. | *29.67 | 6.30 | [a] Cal-500 [PP] | [a] Cal-Sup [IA] |

**CALCIUM Tablet 600 mg (as carbonate), 120**

| 4142B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 1 | .. | *24.13 | 6.30 | CAL-600 [PP] |

## ▪ CALCIUM

**Restricted benefit**
Hypocalcaemia
**Restricted benefit**
Osteoporosis
**Restricted benefit**
Proven calcium malabsorption

**CALCIUM Tablet (chewable) 500 mg (as carbonate), 60**

| 4333C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 1 | .. | *20.37 | 6.30 | [a] Cal-500 [PP] | [a] Cal-Sup [IA] |

**CALCIUM Tablet 600 mg (as carbonate), 120**

| 4082W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 17.61 | 6.30 | CAL-600 [PP] |

### OTHER MINERAL SUPPLEMENTS

*Magnesium*

## ▪ MAGNESIUM ASPARTATE DIHYDRATE

**Restricted benefit**
Hypomagnesaemia
The condition must be documented in the patient's medical records.

**magnesium aspartate dihydrate 500 mg (equivalent to 37.4 mg of magnesium) tablet, 50**

| 4321K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 17.11 | 6.30 | Mag-Sup [PP] |
| | | | .. | 17.68 | 6.30 | Magmin [BB] |

# ▪ BLOOD AND BLOOD FORMING ORGANS

# ▪ ANTITHROMBOTIC AGENTS

### ANTITHROMBOTIC AGENTS

*Platelet aggregation inhibitors excl. heparin*

## ▪ ASPIRIN

**aspirin 100 mg tablet, 90**

| 4076M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 19.13 | 6.30 | Cardiprin 100 [RC] |

**aspirin 100 mg tablet, 112**

| 10590J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 12.93 | 6.30 | Spren 100 [OW] |

## ▪ ASPIRIN

**Note** The enteric coated preparations are for patients with a significant risk of gastrointestinal bleeding.

**aspirin 100 mg enteric capsule, 84**

| 4078P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 18.22 | 6.30 | Astrix [YN] |

**aspirin 100 mg enteric tablet, 84**

| 4077N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 17.43 | 6.30 | Cardasa [AF] | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | [a] Cartia [AS] | [a] Pharmacy Action Low Dose Aspirin [GQ] |

## ▪ CLOPIDOGREL

**Note** Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

**Authority required**

For use in patients pre- and post-angioplasty

**clopidogrel 75 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10169F | 1 | 3 | .. | 15.18 | 6.30 | [a] Clopidogrel GH [GQ] |

**clopidogrel 75 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 4179Y | 1 | 3 | .. | 15.18 | 6.30 | [a] APO-Clopidogrel [TX] | [a] Blooms the Chemist Clopidogrel [IB] |
| | | | | | | [a] Chem mart Clopidogrel [CH] | [a] Clopidogrel AN [EA] |
| | | | | | | [a] Iscover [AV] | [a] Piax [AF] |
| | | | | | | [a] Plavix [SW] | [a] Terry White Chemists Clopidogrel [TW] |

# ▪ ANTIANEMIC PREPARATIONS

## IRON PREPARATIONS

*Iron bivalent, oral preparations*

## ▪ FERROUS FUMARATE

**ferrous fumarate 200 mg (equivalent to 65.7 mg of elemental iron) tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10594N | 1 | 1 | .. | 17.76 | 6.30 | Ferro-tab [AE] |

*Iron in combination with folic acid*

## ▪ FERROUS FUMARATE + FOLIC ACID

**ferrous fumarate 310 mg (equivalent to 100 mg elemental iron) + folic acid 350 microgram tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10579T | 1 | 1 | .. | 18.78 | 6.30 | Ferro-f-tab [AE] |

## VITAMIN B12 AND FOLIC ACID

*Vitamin B12 (cyanocobalamin and analogues)*

## ▪ HYDROXOCOBALAMIN

**Note** One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin $B_{12}$ deficiencies.

**Note** Pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as acetate) in 1 mL and pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as chloride) in 1 mL are equivalent for the purposes of substitution.

**Restricted benefit**

Pernicious anaemia

**Restricted benefit**

Proven vitamin B12 deficiencies other than pernicious anaemia

**Restricted benefit**

Anaemias associated with vitamin B12 deficiency

**Clinical criteria:**

- Patient must have had a gastrectomy, **AND**
- The treatment must be for prophylaxis.

**hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10577Q | 1 | .. | .. | 15.36 | 6.30 | [a] Vita-B12 [GH] |

**hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10587F | 1 | .. | .. | 15.36 | 6.30 | [a] Neo-B12 [PF] |

*Folic acid and derivatives*

### ▪ FOLIC ACID

**folic acid 500 microgram tablet, 100**

| 10584C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | .. | .. | *15.15 | 6.30 | [a] Foltabs 500 [PP] | [a] Megafol 0.5 [AF] |

### ▪ FOLIC ACID

**Note** The 5 mg strength tablet should be used in malabsorption states only.

**folic acid 5 mg tablet, 100**

| 10573L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 1 | .. | *17.37 | 6.30 | Megafol 5 [AF] |

## ▪ BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

### IRRIGATING SOLUTIONS

*Salt solutions*

### ▪ SODIUM CHLORIDE

**sodium chloride 0.9% (9 g/L) solution, 1 L bottle**

| 4461T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 14.77 | 6.30 | Baxter Healthcare Pty Ltd [BX] |

**sodium chloride 0.9% (4.5 g/500 mL) solution, 500 mL bottle**

| 4460R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 14.49 | 6.30 | Baxter Healthcare Pty Ltd [BX] |

## ▪ CARDIOVASCULAR SYSTEM

## ▪ VASOPROTECTIVES

### AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE

*Other agents for treatment of hemorrhoids and anal fissures for topical use*

### ▪ ZINC OXIDE + PERU BALSAM + BENZYL BENZOATE

**zinc oxide 10.75% + peru balsam 1.88% + benzyl benzoate 1.25% ointment, 50 g**

| 4039N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 18.06 | 6.30 | Anusol [JT] |

**zinc oxide 300 mg + peru balsam 50 mg + benzyl benzoate 33 mg suppository, 12**

| 4040P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 17.12 | 6.30 | Anusol [JT] |

## ▪ DERMATOLOGICALS

## ▪ ANTIFUNGALS FOR DERMATOLOGICAL USE

### ANTIFUNGALS FOR TOPICAL USE

*Antibiotics*

### ▪ NYSTATIN

**nystatin 100 000 units/g cream, 15 g**

| 4001N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 16.10 | 6.30 | Mycostatin [FM] |

*Imidazole and triazole derivatives*

### ▪ CLOTRIMAZOLE

**clotrimazole 1% cream, 20 g**

| 4004R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 12.85 | 6.30 | [a] Pharmacy Action Anti-Fungal Cream [GQ] |
| | | | .. | 13.19 | 6.30 | [a] Clonea [AF] |

### ▪ KETOCONAZOLE

**Restricted benefit**

Severe seborrhoeic dermatitis

**ketoconazole 2% shampoo, 100 mL**

| 4007X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 22.35 | 6.30 | Sebizole [EA] |

## ▪ MICONAZOLE

**miconazole nitrate 2% cream, 40 g**

| 3400Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 17.40 | 6.30 | Resolve Thrush [EO] |

*Other antifungals for topical use*

## ▪ AMOROLFINE

**Restricted benefit**

Onychomycosis

**amorolfine 5% application, 5 mL**

| 4010C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 47.65 | 6.30 | [a] Myconail [AE] |
| | | | .. | 61.08 | 6.30 | [a] Sandoz Nail Repair [SZ] |
| | | | .. | 67.73 | 6.30 | [a] Pharmacy Action Anti-Fungal Nail Treatment [GQ] |
| | | | .. | 83.90 | 6.30 | [a] Aporyl [TX] |
| | | | .. | 92.65 | 6.30 | [a] Loceryl [GA] |

## ▪ TERBINAFINE

**Restricted benefit**

Tinea pedis

**terbinafine hydrochloride 1% cream, 15 g**

| 4473K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 24.54 | 6.30 | [a] Lamisil [GK] | [a] Pharmacy Action Pharmisil [GQ] |

**terbinafine 1% gel, 15 g**

| 4463X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 25.81 | 6.30 | Lamisil DermGel [GK] |

## ▪ TOLNAFTATE

**tolnaftate 0.07% spray, 100 g**

| 4481W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 18.63 | 6.30 | Tinaderm [BN] |

# ANTIFUNGALS FOR SYSTEMIC USE

*Antifungals for systemic use*

## ▪ TERBINAFINE

**Authority required**

Onychomycosis

**Clinical criteria:**

- The condition must be due to dermatophyte infection proven by microscopy and confirmed by an Approved Pathology Provider; OR
- The condition must be due to dermatophyte infection proven by culture and confirmed by an Approved Pathology Provider.

**terbinafine 250 mg tablet, 42**

| 4011D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 30.00 | 6.30 | [a] GenRx Terbinafine [GX] | [a] Lamisil (Novartis Pharmaceuticals Australia Pty Limited) [NV] |
| | | | | | | [a] Tamsil [RW] | [a] Terbinafine GH [GQ] |
| | | | | | | [a] Terbinafine Sandoz [SZ] | [a] Tinasil [AF] |

# ▪ EMOLLIENTS AND PROTECTIVES

## EMOLLIENTS AND PROTECTIVES

*Silicone products*

RPBS

## ▪ DIMETHICONE-350 + GLYCEROL

**Restricted benefit**
For colostomy and ileostomy use
**Restricted benefit**
For use by paraplegic and quadriplegic patients
**Restricted benefit**
For use with surgical appliances

**dimethicone-350 15% + glycerol 2% cream, 500 g**

| 4551M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 28.47 | 6.30 | Silic 15 [EO] |

**dimethicone-350 15% + glycerol 2% cream, 75 g**

| 4556T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 16.40 | 6.30 | Silic 15 [EO] |

*Soft paraffin and fat products*

## ▪ WOOL ALCOHOLS

**wool alcohols 6% ointment, 100 g**

| 4041Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 17.84 | 6.30 | Eucerin [BE] |

*Carbamide products*

## ▪ UREA

**urea 10% cream, 100 g**

| 4042R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 16.11 | 6.30 | Aquacare H.P. [AG] |
| | | | .. | 16.33 | 6.30 | Urederm [IA] |
| | | | .. | 16.61 | 6.30 | Calmurid [OL] |

*Other emollients and protectives*

## ▪ CARMELLOSE SODIUM + GELATIN + PECTIN

**carmellose sodium 16.7% + gelatin 16.7% + pectin 16.7% oromucosal paste, 5 g**

| 4518T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 15.81 | 6.30 | Orabase [QA] |

## ▪ SKIN EMOLLIENT

**SKIN EMOLLIENT Bath oil 500 mL, 1**

| 4122Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 20.59 | 6.30 | Alpha Keri Bath Oil [MT] |
| | | | .. | 22.69 | 6.30 | QV Bath Oil [EO] |
| | | | .. | 22.77 | 6.30 | Hamilton Skin Therapy Oil [KY] |

**SKIN EMOLLIENT Lotion 500 mL, 1**

| 4107E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 20.59 | 6.30 | Alpha Keri Lotion [MT] |

# PROTECTIVES AGAINST UV-RADIATION

*Protectives against UV-radiation for topical use*

## ▪ SUNSCREENS

**SUNSCREENS Lotion (non-alcoholic) 125 mL, 1**

| 4546G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 19.40 | 6.30 | Aquasun Lotion SPF 18 [PF] |
| | | | .. | 21.20 | 6.30 | Sunsense Ultra SPF 50+ [EO] |

**SUNSCREENS Cream 75 g, 1**

| 4307Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 21.20 | 6.30 | Sunsense Sensitive SPF 50+ [EO] |

# ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

## ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

*Anesthetics for topical use*

### LIGNOCAINE

**lignocaine hydrochloride anhydrous 2% oral liquid, 200 mL**

4308R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 103.21 | 6.30 | Xylocaine Viscous [QA] |

*Other antipruritics*

### PINE TAR WITH TRIETHANOLAMINE LAURYL SULFATE

**Note** For patients who have failed to respond to simple moisturising agents.

**PINE TAR with TRIETHANOLAMINE LAURYL SULFATE Solution 23 mg-60 mg per mL (2.3%-6%), 500 mL, 1**

4408B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 25.44 | 6.30 | Pinetarsol [EO] |

# ANTIPSORIATICS

## ANTIPSORIATICS FOR TOPICAL USE

*Tars*

### COAL TAR SOLUTION + PHENOL + PRECIPITATED SULFUR

**coal tar solution 5% + phenol 0.5% + precipitated sulfur 0.5% gel, 30 g**

4505D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 19.44 | 6.30 | Egopsoryl-TA [EO] |

# ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

## ANTIBIOTICS FOR TOPICAL USE

*Other antibiotics for topical use*

### MUPIROCIN

**Restricted benefit**

Secondarily infected traumatic skin lesions

**mupirocin 2% cream, 15 g**

4348W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 20.51 | 6.30 | Bactroban [GK] |

**mupirocin 2% ointment, 15 g**

4350Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 20.51 | 6.30 | Bactroban [GK] |

## CHEMOTHERAPEUTICS FOR TOPICAL USE

*Antivirals*

### PODOPHYLLOTOXIN

**Authority required**

Ano-genital warts

**podophyllotoxin 0.15% cream, 5 g**

4390C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 52.83 | 6.30 | Wartec Cream [GK] |

*Other chemotherapeutics*

### INGENOL MEBUTATE

**Authority required**

Solar keratosis

**Clinical criteria:**

- Patient must require topical drug therapy on the face and scalp as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

**ingenol mebutate 0.015% gel, 3 x 470 mg**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2464Q | 1 | .. | .. | 138.90 | 6.30 | Picato [LO] |

### ▪ INGENOL MEBUTATE

**Authority required**

Solar (actinic) keratosis

**Clinical criteria:**

- Patient must require topical drug therapy as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

**ingenol mebutate 0.05% gel, 2 x 470 mg**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2468X | 1 | .. | .. | 138.90 | 6.30 | Picato [LO] |

## ▪ CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

### CORTICOSTEROIDS, PLAIN

*Corticosteroids, weak (group I)*

### ▪ HYDROCORTISONE ACETATE

**Restricted benefit**

Corticosteroid-responsive dermatoses

**hydrocortisone acetate 1% ointment, 30 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10831C | ‡1 | 1 | .. | 16.26 | 6.30 | Cortic-DS 1% [QA] |

*Corticosteroids, potent (group III)*

### ▪ BETAMETHASONE VALERATE

**betamethasone (as valerate) 0.1% ointment, 30 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4132L | ‡1 | 2 | .. | 25.01 | 6.30 | Betnovate [QA] |

**betamethasone (as valerate) 0.1% cream, 30 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4131K | ‡1 | 2 | .. | 25.01 | 6.30 | Betnovate [QA] |

### ▪ MOMETASONE

**Note** Application to large areas of skin for longer than four weeks is not recommended.

**mometasone furoate 0.1% cream, 50 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4342M | ‡1 | .. | .. | 34.62 | 6.30 | Elocon [MK] |

**mometasone furoate 0.1% ointment, 50 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4343N | ‡1 | .. | .. | 34.62 | 6.30 | Elocon [MK] |

## ▪ ANTISEPTICS AND DISINFECTANTS

### ANTISEPTICS AND DISINFECTANTS

*Iodine products*

### ▪ POVIDONE-IODINE

**povidone-iodine 10% solution, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4411E | ‡1 | .. | .. | 24.73 | 6.30 | Betadine Antiseptic Liquid [SW] |

## ▪ OTHER DERMATOLOGICAL PREPARATIONS

### OTHER DERMATOLOGICAL PREPARATIONS

*Medicated shampoos*

## ▪ COAL TAR SOLUTION + TAR + SALICYLIC ACID

**coal tar solution 1% + tar 1% + salicylic acid 2% solution, 250 mL**

| 4447C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 21.89 | 6.30 | Sebitar [EO] |

## ▪ SALICYLIC ACID + BENZALKONIUM CHLORIDE + ALCOHOL + COAL TAR SOLUTION + POLYOXYETHYLENE ETHERS

**SALICYLIC ACID with COAL TAR SOLUTION Scalp cleanser 20 mg-50 mg per mL (2%-5%), 200 mL, 1**

| 4560B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 23.23 | 6.30 | Ionil-T [GA] |

## ▪ SELENIUM SULFIDE

**selenium sulfide 2.5% shampoo, 125 mL**

| 4452H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 17.80 | 6.30 | Selsun [DQ] |

## ▪ TAR + CADE OIL + COAL TAR + ARACHIS OIL EXTRACT OF COAL TAR

**tar 0.3% (300 microgram/mL) + cade oil 0.03% (300 microgram/mL) + coal tar 0.01% (100 microgram/mL) + arachis oil extract of coal tar 0.3% (3 mg/mL) lotion, 300 mL**

| 4405W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 26.50 | 6.30 | Polytar [GK] |

*Wart and anti-corn preparations*

## ▪ SALICYLIC ACID + LACTIC ACID

**salicylic acid 16.7% + lactic acid 16.7% application, 15 mL**

| 4386W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 21.29 | 6.30 | Duofilm Solution [GK] |

*Other dermatologicals*

## ▪ DICLOFENAC

**Note** Maximum quantity of four tubes (original + 3 repeats) in 12 months.

**Authority required**

Solar (actinic) keratosis

Treatment Phase: Management

**Clinical criteria:**

- Patient must require topical drug therapy as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

**diclofenac sodium 3% gel, 25 g**

| 4046Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 3 | .. | 58.15 | 6.30 | Solaraze 3% Gel [FK] |

## ▪ ICHTHAMMOL

**Note** For patients who have failed to respond to simple moisturising agents.

**ichthammol Cream 5 mg-10 mg-10 mg per g (0.5%-1%-1%), 50 g, 1**

| 4281H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 21.25 | 6.30 | Egoderm Cream [EO] |

## ▪ ICHTHAMMOL + ZINC OXIDE

**Note** For patients who have failed to respond to simple moisturising agents.

**ichthammol 1% + zinc oxide 15% ointment, 50 g**

| 4280G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 21.25 | 6.30 | Egoderm Ointment [EO] |

## ▪ IMIQUIMOD

**Authority required**

Superficial basal cell carcinoma

Treatment Phase: Primary treatment

**Clinical criteria:**

- The condition must be confirmed by a histological diagnosis, **AND**

- The condition must be one where other standard treatments are inappropriate, **AND**
- The condition must require topical drug therapy.

**imiquimod 5% cream, 12 x 250 mg sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 4559Y | 1 | 1 | .. | 86.62 | 6.30 | [a] Aldiq [QA] | [a] APO-Imiquimod [TX] |
| | | | .. | 88.90 | 6.30 | [a] Aldara [IA] | |

## ▪ IMIQUIMOD

**Note** Pharmaceutical benefits that have the form imiquimod single use sachets and pharmaceutical benefits that have the form imiquimod multi-use pump are equivalent for the purposes of substitution.

**Authority required**

Solar keratosis

**Clinical criteria:**

- Patient must require topical drug therapy on the face and scalp as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

**imiquimod 5% cream, 2 x 2 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10106X | 1 | 1 | .. | 91.17 | 6.30 | [a] Aldara Pump [IA] |

**imiquimod 5% cream, 12 x 250 mg sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 4134N | 1 | 1 | .. | 86.62 | 6.30 | [a] Aldiq [QA] | [a] APO-Imiquimod [TX] |
| | | | .. | 88.90 | 6.30 | [a] Aldara [IA] | |

## ▪ LIGHT LIQUID PARAFFIN + COCOAMPHODIACETATE DISODIUM

**light liquid paraffin 3.5% + cocoamphodiacetate disodium 3% lotion, 500 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4549K | ‡1 | 2 | .. | 23.54 | 6.30 | Hamilton Skin Therapy Wash [KY] |

## ▪ PANTHENOL

**Note** To be used in conjunction with the scalp cleanser salicylic acid with coal tar solution and pine tar (code 4447C).

**panthenol conditioner, 200 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4510J | ‡1 | 2 | .. | 17.90 | 6.30 | SebiRinse [EO] |

## ▪ ZINC OXIDE + MAIZE STARCH + CHLORPHENESIN + PURIFIED TALC

**zinc oxide 25% + maize starch 55.85% + chlorphenesin 1% + purified talc 18.07% dusting powder, 100 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4497Q | ‡1 | 1 | .. | 16.16 | 6.30 | Z.S.C. [RW] |

# ▪ GENITO URINARY SYSTEM AND SEX HORMONES

# ▪ GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS

## ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS

*Antibiotics*

## ▪ NYSTATIN

**nystatin 20 000 units/g vaginal cream, 75 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4013F | ‡1 | 1 | .. | 17.50 | 6.30 | Nilstat [QA] |

*Imidazole derivatives*

## ▪ CLOTRIMAZOLE

**clotrimazole 2% vaginal cream, 20 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 4017K | ‡1 | .. | .. | 18.62 | 6.30 | APO-Clotrimazole 3 Day Cream [TX] | Clonea 3 Day Cream [AF] |

RPBS

**clotrimazole 1% vaginal cream, 35 g**

| 4016J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 17.41 | 6.30 | [a] Clonea 6 Day Cream [AF] | [a] Pharmacy Action FemCream [GQ] |
| | | | .. | 18.62 | 6.30 | [a] APO-Clotrimazole 6 Day Cream [TX] | |

# ▪ OTHER GYNECOLOGICALS

## OTHER GYNECOLOGICALS

### ▪ ACETIC ACID + HYDROXYQUINOLINE + RICINOLEIC ACID

**acetic acid 0.94% + hydroxyquinoline sulfate 0.025% + ricinoleic acid 0.75% vaginal gel, 100 g**

| 4434J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 34.12 | 6.30 | Aci-Jel [CU] |

# ▪ UROLOGICALS

## UROLOGICALS

*Drugs used in erectile dysfunction*

### ▪ ALPROSTADIL

**Authority required**

Erectile dysfunction

**Clinical criteria:**

- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

**Population criteria:**

- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

**alprostadil 10 microgram injection [2] (&) inert substance diluent [2 x 0.6 mL syringes], 1 pack**

| 4579B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 3 | .. | *101.14 | 6.30 | Caverject Impulse [PF] |

**alprostadil 20 microgram injection [2] (&) inert substance diluent [2 x 0.6 mL syringes], 1 pack**

| 4580C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 3 | .. | *125.98 | 6.30 | Caverject Impulse [PF] |

### ▪ SILDENAFIL

**Authority required**

Erectile dysfunction

**Clinical criteria:**

- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

**Population criteria:**

- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

**sildenafil 25 mg tablet, 4**

| 4584G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 55.04 | 6.30 | [a] Sildenafil Actavis [EA] | [a] Vasafil 25 [RW] |
| | | | | | | [a] Vedafil [AF] | |
| | | | .. | 55.05 | 6.30 | [a] APO-Sildenafil [TX] | |
| | | | .. | 63.42 | 6.30 | [a] Viagra [PF] | |

**sildenafil 50 mg tablet, 4**

| 4585H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 67.04 | 6.30 | [a] APO-Sildenafil [TX] | [a] Sildenafil Actavis [EA] |
| | | | | | | [a] Vasafil 50 [RW] | [a] Vedafil [AF] |
| | | | .. | 77.70 | 6.30 | [a] Viagra [PF] | |

**sildenafil 100 mg tablet, 4**

| 4586J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 71.61 | 6.30 | [a] APO-Sildenafil [TX]<br>[a] Sildenafil Actavis [EA]<br>[a] Terry White Chemists Sildenafil [TW]<br>[a] Vedafil [AF] | [a] Chem mart Sildenafil [CH]<br>[a] Sildenafil generichealth [GQ]<br>[a] Vasafil 100 [RW] |
| | | | .. | 83.14 | 6.30 | [a] Silaran [RA] | [a] Viagra [PF] |

## ▪ TADALAFIL

**Authority required**

Erectile dysfunction

**Clinical criteria:**

- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

**Population criteria:**

- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

**tadalafil 20 mg tablet, 4**

| 4597Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 103.85 | 6.30 | Cialis [LY] |

**tadalafil 10 mg tablet, 4**

| 4596X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 103.85 | 6.30 | Cialis [LY] |

## ▪ VARDENAFIL

**Authority required**

Erectile dysfunction

**Clinical criteria:**

- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

**Population criteria:**

- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

**vardenafil 20 mg tablet, 4**

| 4302K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 81.18 | 6.30 | Levitra [BN] |

**vardenafil 10 mg tablet, 4**

| 4290T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 71.43 | 6.30 | Levitra [BN] |

*Other urologicals*

RPBS

## ▪ BICARBONATE + CITRIC ACID + TARTARIC ACID

**Restricted benefit**

Urinary symptoms

**Clinical criteria:**

- The treatment must be for when antibiotic or other therapy alone is inappropriate.

**sodium bicarbonate 1.76 g + sodium citrate 630 mg + citric acid 720 mg + tartaric acid 890 mg powder for oral liquid, 28 x 4 g sachets**

| 4049D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | ‡1 | 4 | .. | 17.29 | 6.30 | Uracol [EA] | Ural Sachets [QA] |

## DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY

*Alpha-adrenoreceptor antagonists*

## ▪ ALFUZOSIN

**Authority required**

Benign prostatic hyperplasia

**Clinical criteria:**

- Patient must be one in whom surgery is inappropriate; OR
- Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

**alfuzosin hydrochloride 10 mg modified release tablet, 30**

4277D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 62.85 | 6.30 | Xatral SR [SW] |

## ▪ DUTASTERIDE + TAMSULOSIN

**Authority required**

Benign prostatic hyperplasia

**Clinical criteria:**

- Patient must be one in whom surgery is inappropriate; OR
- Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

**dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30**

10102Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 35.14 | 6.30 | Duodart 500ug/400ug [GK] |

## ▪ TAMSULOSIN

**Authority required**

Benign prostatic hyperplasia

**Clinical criteria:**

- Patient must be one in whom surgery is inappropriate; OR
- Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

**tamsulosin hydrochloride 400 microgram modified release tablet, 30**

4070F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 62.85 | 6.30 | Flomaxtra [LS] | Tamsulosin Sandoz SR [SZ] |

*Testosterone-5-alpha reductase inhibitors*

## ▪ DUTASTERIDE

**Authority required**

Benign prostatic hyperplasia

**Clinical criteria:**

- Patient must be one in whom surgery is inappropriate; OR
- Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

**dutasteride 500 microgram capsule, 30**

10095H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 30.93 | 6.30 | Avodart [GK] |

## ▪ FINASTERIDE

**Authority required**

Benign prostatic hyperplasia

**Clinical criteria:**

- Patient must be one in whom surgery is inappropriate; OR
- Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

**finasteride 5 mg tablet, 30**

4233T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 75.88 | 6.30 | [a] Auro-Finasteride [DO] | [a] Finasteride AN [EA] |
| | | | | | [a] Finasteride GH 5 [GQ] | [a] Finide [AL] |
| | | .. | 93.73 | 6.30 | [a] Finnacar [RW] | |
| | | .. | 98.08 | 6.30 | [a] APO-Finasteride [TX] | [a] Finasta [SZ] |
| | | | | | [a] Finasteride Alphapharm [AF] | [a] Finasteride-GA 5 [GN] |
| | | | | | [a] Pharmacor Finasteride 5 [CR] | [a] Proscar [MK] |

**finasteride 5 mg tablet, 28**

4303L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 88.22 | 6.30 | [a] Finpro [RZ] | [a] Pharmacy Choice Finasteride [RI] |

# ANTIINFECTIVES FOR SYSTEMIC USE

## ANTIBACTERIALS FOR SYSTEMIC USE

### MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

*Macrolides*

#### AZITHROMYCIN

**Restricted benefit**

Upper and lower respiratory tract infections

**azithromycin 500 mg tablet, 3**

4115N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 32.91 | 6.30 | Zedd 500 [RW]<br>[a] APO-Azithromycin [TX]<br>[a] Azithromycin Sandoz [SZ]<br>[a] Terry White Chemists Azithromycin [TW]<br>[a] Zitrocin [GN] | [a] Azithromycin-GA [EA]<br>[a] Chem mart Azithromycin [CH]<br>[a] Zithromax [PF] |

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

## ANTINEOPLASTIC AGENTS

### ANTIMETABOLITES

*Pyrimidine analogues*

#### FLUOROURACIL

**fluorouracil 5% cream, 20 g**

4222F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | .. | .. | 65.28 | 6.30 | [a] APOC-5FU [TX] | [a] Efudix [IA] |

## IMMUNOSUPPRESSANTS

### IMMUNOSUPPRESSANTS

*Tumor necrosis factor alpha (TNF-) inhibitors*

#### INFLIXIMAB

**Note** Any queries concerning the arrangements to prescribe infliximab may be directed to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) on 1800 552 580.

Written applications for authority to prescribe infliximab should be forwarded to:
Reply Paid 9998
Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC)
Department of Veterans' Affairs
GPO Box 9998
BRISBANE QLD 4001

**Authority required**

Initial treatment, in combination with methotrexate, of specific accepted war-caused or service-related disability of refractory rheumatoid arthritis. Initial treatment may be prescribed by rheumatologists or consultant physicians for the reduction of signs and symptoms and prevention of structural joint damage in adult patients with active rheumatoid arthritis who satisfy all of the following criteria:

(1) (a) Proven raised erythrocyte sedimentation rate (ESR) and/or C-reactive protein (CRP); and

(1) (b) Proven erosive rheumatoid arthritis without end-stage disease;

(2) Failure of an adequate trial of methotrexate and 2 other disease modifying anti-rheumatic drugs (such as sulfasalazine, hydroxychloroquine, leflunomide or cyclosporin) — unless these drugs were contraindicated or intolerance had developed;

(3) No history of active tuberculosis requiring treatment in the last 3 years;

(4) No history of opportunistic infection in the last 2 months;

(5) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form)

**Authority required**

Continuing treatment, in combination with methotrexate, of specific accepted war-caused or service-related disability of refractory rheumatoid arthritis. Continuing treatment may be prescribed by rheumatologists or consultant physicians, following initial therapy of 3 doses, in patients who satisfy the following criteria:

(1) There is improvement in ESR and/or CRP; and

(2) An ACR20 (American College of Rheumatology) response is achieved by 14 weeks after the commencement of therapy.
Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form)

**infliximab 100 mg injection, 1 vial**

| 4284L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 569.47 | 6.30 | Remicade [JC] |

# ▪ MUSCULO-SKELETAL SYSTEM

## ▪ TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

### TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

*Preparations with salicylic acid derivatives*

### ▪ EUCALYPTUS OIL + MENTHOL + METHYL SALICYLATE

**eucalyptus oil 10% + menthol 4% + methyl salicylate 25% cream, 100 g**

| 4022Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 17.70 | 6.30 | Gold Cross [BI] |

### ▪ METHYL SALICYLATE

**methyl salicylate 50% ointment, 100 g**

| 4023R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 16.09 | 6.30 | Gold Cross [BI] |

**methyl salicylate 25% liniment, 100 mL**

| 4026X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 14.15 | 6.30 | Gold Cross [BI] |

## ▪ DRUGS FOR TREATMENT OF BONE DISEASES

### DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

*Bisphosphonates*

### ▪ RISEDRONATE

**Authority required**

Preservation of bone mineral density

**Clinical criteria:**

- Patient must be on long-term glucocorticoid therapy, **AND**
- Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
- Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

**risedronate sodium 5 mg tablet, 28**

| 4443W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 35.10 | 6.30 | Actonel [UA] |

**risedronate sodium 35 mg tablet, 4**

| 4444X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 35.10 | 6.30 | [a] Acris Once-a-Week [AF]<br>[a] Risedronate AN [EA]<br>[a] Risedronate Sandoz [SZ] | [a] APO-Risedronate [TX]<br>[a] Risedronate-GA [GN]<br>[a] Risedro once a week [RW] |

**RISEDRONATE SODIUM Tablet 35 mg (enteric coated), 4**

| 2191H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 35.10 | 6.30 | Actonel EC [UA] |

*Bisphosphonates, combinations*

### ▪ ALENDRONATE + COLECALCIFEROL

**Authority required**

Preservation of bone mineral density

**Clinical criteria:**

- Patient must be on long-term glucocorticoid therapy, **AND**

RPBS

- Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
- Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

**alendronate 70 mg + colecalciferol 140 microgram tablet, 4**

2224C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 15.00 | 6.30 | [a] Alendronate plus D3-DRLA [RZ]<br>[a] Chem mart Alendronate Plus D3 70 mg/140 mcg [CH]<br>[a] Terry White Chemists Alendronate Plus D3 70 mg/140 mcg [TW] | [a] APO-Alendronate Plus D3 70 mg/140 mcg [TX]<br>[a] FonatPlus [AF] |
| | | .. | 20.20 | 6.30 | [a] Fosamax Plus 70 mg/140 mcg [MK] | |

**alendronate 70 mg + colecalciferol 70 microgram tablet, 4**

2194L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 15.00 | 6.30 | [a] Alendronate plus D3-DRLA [RZ]<br>[a] Chem mart Alendronate Plus D3 70 mg/70 mcg [CH]<br>[a] Terry White Chemists Alendronate Plus D3 70 mg/70 mcg [TW] | [a] APO-Alendronate Plus D3 70 mg/70 mcg [TX]<br>[a] FonatPlus [AF] |
| | | .. | 20.20 | 6.30 | [a] Fosamax Plus [MK] | |

## ▪ ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE

**Authority required**

Preservation of bone mineral density

**Clinical criteria:**

- Patient must be on long-term glucocorticoid therapy, **AND**
- Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
- Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

**alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack**

2273P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 15.46 | 6.30 | [a] APO-Alendronate Plus D3 and Calcium [TX] |
| | | .. | 24.71 | 6.30 | [a] Fosamax Plus D-Cal [MK] |

## ▪ RISEDRONATE (&) CALCIUM CARBONATE

**Authority required**

Preservation of bone mineral density

**Clinical criteria:**

- Patient must be on long-term glucocorticoid therapy, **AND**
- Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
- Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

**risedronate sodium 35 mg tablet [4] (&) calcium (as carbonate) 500 mg tablet [24], 28**

4059P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 35.10 | 6.30 | Acris Combi [AF] |

**RISEDRONATE SODIUM and CALCIUM CARBONATE Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1**

2220W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 35.10 | 6.30 | Actonel EC Combi [UA] |

## ▪ RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL

**Authority required**

Preservation of bone mineral density

**Clinical criteria:**

- Patient must be on long-term glucocorticoid therapy, **AND**

- Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
- Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

**RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, 1**

| 2254P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 5 | .. | 35.10 | 6.30 | Actonel EC Combi D [UA] |

# NERVOUS SYSTEM

## ANALGESICS

### OPIOIDS

*Natural opium alkaloids*

#### MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain where treatment has been initiated by a specialist with appropriate expertise in pain management.

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**morphine sulfate 200 mg modified release tablet, 28**

| 4349X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 116.58 | 6.30 | MS Contin [MF] |

*Opioids in combination with non-opioid analgesics*

#### ASPIRIN + CODEINE

**aspirin 300 mg + codeine phosphate 8 mg dispersible tablet, 40**

| 4286N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 17.84 | 6.30 | Aspalgin 40 [QA] |

#### PARACETAMOL + CODEINE

**paracetamol 500 mg + codeine phosphate 8 mg tablet, 50**

| 4171M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 16.69 | 6.30 | Codalgin [FM] |

**paracetamol 500 mg + codeine phosphate hemihydrate 15 mg tablet, 20**

| 10186D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 13.97 | 6.30 | Pharmacy Action Paracetamol Plus Codeine [GQ] |

**paracetamol 500 mg + codeine phosphate 8 mg tablet, 40**

| 4275B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 14.80 | 6.30 | Panamax Co. 40 [SW] |

### OTHER ANALGESICS AND ANTIPYRETICS

*Anilides*

#### PARACETAMOL

**paracetamol 240 mg/5 mL oral liquid, 200 mL**

| 10599W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 14.79 | 6.30 | Panamax 240 Elixir [SW] |

**paracetamol 500 mg tablet, 100**

| 10582Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 12.74 | 6.30 | [a] APO-Paracetamol [TX]<br>[a] Generic Health Pty Ltd [GQ] | [a] Febridol [EA]<br>[a] Panamax [SW] |

RPBS

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | [a] Paracetamol (Sandoz) [SZ]<br>[a] Parapane [AF] | [a] Paralgin [OW] |

## ▪ PARACETAMOL

**Restricted benefit**

Persistent pain

**Clinical criteria:**

- The condition must be associated with osteoarthritis.

**paracetamol 665 mg modified release tablet, 96**

| 10598T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *18.55 | 6.30 | Osteomol 665 Paracetamol [CR] |

## ▪ PARACETAMOL

**Restricted benefit**

Chronic arthropathies

**paracetamol 500 mg tablet, 100**

| 10585D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 3 | 4 | .. | *16.03 | 6.30 | [a] APO-Paracetamol [TX]<br>[a] Generic Health Pty Ltd [GQ]<br>[a] Paracetamol (Sandoz) [SZ]<br>[a] Parapane [AF] | [a] Febridol [EA]<br>[a] Panamax [SW]<br>[a] Paralgin [OW] |

*Other analgesics and antipyretics*

## ▪ GABAPENTIN

**Authority required**

Refractory neuropathic pain

**Clinical criteria:**

- The condition must be unable to be controlled by other drugs.

**gabapentin 100 mg capsule, 100**

| 4591P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 15.13 | 6.30 | [a] APO-Gabapentin [TX]<br>[a] Neurontin [PF] | [a] Gabapentin Aspen 100 [RW]<br>[a] Nupentin 100 [AF] |

**gabapentin 400 mg capsule, 100**

| 4593R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 29.50 | 6.30 | [a] Gabapentin 400 [CR]<br>[a] Gabapentin GH [GQ]<br>[a] GenRx Gabapentin [GX]<br>[a] Nupentin 400 [AF] | [a] Gabapentin Aspen 400 [RW]<br>[a] Gantin [EA]<br>[a] Neurontin [PF] |

**gabapentin 600 mg tablet, 100**

| 4594T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 40.31 | 6.30 | [a] Gabapentin AN [EA]<br>[a] GenRx Gabapentin [GX]<br>[a] Nupentin Tabs [AF] | [a] Gabapentin Aspen 600 [RW]<br>[a] Neurontin [PF] |

**gabapentin 300 mg capsule, 100**

| 4592Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 24.59 | 6.30 | [a] Gabapentin 300 [CR]<br>[a] Gabapentin GH [GQ]<br>[a] GenRx Gabapentin [GX]<br>[a] Nupentin 300 [AF] | [a] Gabapentin Aspen 300 [RW]<br>[a] Gantin [EA]<br>[a] Neurontin [PF] |

**gabapentin 800 mg tablet, 100**

| 4595W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 50.06 | 6.30 | [a] Gabapentin AN [EA]<br>[a] Gantin [ED]<br>[a] Neurontin [PF] | [a] Gabapentin Aspen 800 [RW]<br>[a] GenRx Gabapentin [GX]<br>[a] Nupentin Tabs [AF] |

# ▪ PSYCHOLEPTICS

## ANXIOLYTICS

*Benzodiazepine derivatives*

## ▪ BROMAZEPAM

**Note** This drug should not be used as the first line of treatment.

**Note** Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate.
**Note** Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

**Authority required**
Terminal disease
**Clinical criteria:**
- The treatment must be for the short-term, **AND**
- Patient must be receiving palliative care.

**Authority required**
Refractory phobic or anxiety states
**Clinical criteria:**
- The treatment must be for the short-term.

**bromazepam 6 mg tablet, 30**

| 4151L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *36.89 | 6.30 | Lexotan [RO] |

**bromazepam 3 mg tablet, 30**

| 4150K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *31.15 | 6.30 | Lexotan [RO] |

*Azaspirodecanedione derivatives*

## ▪ BUSPIRONE

**Authority required**
Anxiety
**Clinical criteria:**
- The treatment must be for the short-term.

**buspirone hydrochloride 5 mg tablet, 50**

| 4144D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 38.54 | 6.30 | Buspar [QA] |

**buspirone hydrochloride 10 mg tablet, 50**

| 4145E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 55.01 | 6.30 | Buspar [QA] |

# HYPNOTICS AND SEDATIVES

*Benzodiazepine derivatives*

## ▪ FLUNITRAZEPAM

**Note** This drug should not be used as the first line of treatment.
**Note** Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate.
**Note** Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

**Authority required**
Terminal disease
**Clinical criteria:**
- The treatment must be for the short-term, **AND**
- Patient must be receiving palliative care.

**Authority required**
Refractory phobic or anxiety states
**Clinical criteria:**
- The treatment must be for the short-term.

**flunitrazepam 1 mg tablet, 30**

| 4216X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 19.10 | 6.30 | Hypnodorm [AF] |

*Benzodiazepine related drugs*

## ▪ ZOPICLONE

**Restricted benefit**
Insomnia
**Clinical criteria:**
- The treatment must be for the short-term.

**zopiclone 7.5 mg tablet, 30**

| 4522B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | .. | .. | 24.43 | 6.30 | [a] APO-Zopiclone [TX] | [a] Chem mart Zopiclone [CH] |
| | | | | | | [a] Imrest [AF] | [a] Terry White Chemists Zopiclone [TW] |
| | | | | | | [a] Zopiclone GH [GQ] | |
| | | | .. | 27.17 | 6.30 | [a] Imovane [SW] | |

# OTHER NERVOUS SYSTEM DRUGS

## DRUGS USED IN ADDICTIVE DISORDERS

*Drugs used in nicotine dependence*

### NICOTINE

**Note** Studies have shown that successful therapy with this drug is enhanced by patient participation in a support and counselling program.

**Authority required**

Nicotine dependence

**Clinical criteria:**

- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must have entered a comprehensive support and counselling program.

**nicotine 7 mg/24 hours patch, 7**

| 4571N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *51.57 | 6.30 | QuitX [AF] |

**nicotine 14 mg/24 hours patch, 7**

| 4572P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *54.73 | 6.30 | QuitX [AF] |
| | | | .. | *67.75 | 6.30 | Nicabate CQ 14 [GC] |

**nicotine 21 mg/24 hours patch, 7**

| 4573Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 2 | .. | *57.69 | 6.30 | QuitX [AF] |
| | | | .. | *67.75 | 6.30 | Nicabate CQ 21 [GC] |

**nicotine 5 mg/16 hours patch, 7**

| 4576W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *50.97 | 6.30 | Nicorette Patch [JT] |

**nicotine 15 mg/16 hours patch, 7**

| 4578Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 2 | .. | *59.77 | 6.30 | Nicorette Patch [JT] |

**nicotine 10 mg/16 hours patch, 7**

| 4577X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *54.95 | 6.30 | Nicorette Patch [JT] |

# ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

# ANTHELMINTICS

## ANTINEMATODAL AGENTS

*Benzimidazole derivatives*

### MEBENDAZOLE

**mebendazole 100 mg tablet, 6**

| 4325P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 17.29 | 6.30 | Pharmacy Action Worm Treatment [GQ] |

# RESPIRATORY SYSTEM

# NASAL PREPARATIONS

## DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE

*Sympathomimetics, plain*

### ▪ OXYMETAZOLINE

**oxymetazoline hydrochloride 0.05% nasal spray, 18 mL**

| 4379L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 20.08 | 6.30 | Logicin Rapid Relief [QA] |

**oxymetazoline hydrochloride 0.05% nasal spray, 15 mL**

| 4378K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 20.42 | 6.30 | Drixine [BN] |

*Antiallergic agents, excl. corticosteroids*

### ▪ CROMOGLYCATE

**sodium cromoglycate 2% nasal spray, 26 mL**

| 4468E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 5 | .. | 25.43 | 6.30 | Rynacrom [SW] |

### ▪ LEVOCABASTINE

**levocabastine 0.05% nasal spray, 100 actuations**

| 4311X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 21.37 | 6.30 | Livostin [JT] |

*Corticosteroids*

### ▪ BUDESONIDE

**Restricted benefit**
Severe intractable rhinitis

**budesonide 64 microgram/actuation nasal spray, 120 actuations**

| 4092J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 41.68 | 6.30 | Budamax Aqueous [PM] |

*Other nasal preparations*

### ▪ IPRATROPIUM

**Restricted benefit**
Severe intractable rhinorrhoea
**Clinical criteria:**

- The condition must be associated with perennial rhinitis, **AND**
- The condition must be unresponsive to insufflated nasal steroids.

**ipratropium bromide monohydrate 22 microgram/actuation nasal spray, 180 actuations**

| 4089F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 5 | .. | 26.48 | 6.30 | Atrovent Nasal Aqueous [VZ] |

**ipratropium bromide monohydrate 44 microgram/actuation nasal spray, 180 actuations**

| 4090G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 5 | .. | 32.63 | 6.30 | Atrovent Nasal Forte [VZ] |

## NASAL DECONGESTANTS FOR SYSTEMIC USE

*Sympathomimetics*

### ▪ PSEUDOEPHEDRINE

**pseudoephedrine hydrochloride 60 mg tablet, 12**

| 4029C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 14.44 | 6.30 | [a] Pharmacy Action Sinus & Nasal Decongestant Relief [GQ] |
| | | | .. | 15.09 | 6.30 | [a] Logicin Sinus [QA] |

# ▪ COUGH AND COLD PREPARATIONS

## EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

*Expectorants*

RPBS

### ▪ AMMONIUM + SENEGA ROOT

**ammonium bicarbonate 25 mg/mL + senega root 25 mg/mL oral liquid, 200 mL**

| 4074K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 4 | .. | 13.49 | 6.30 | Gold Cross [BI] |

## COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS

*Opium alkaloids and derivatives*

### ▪ PHOLCODINE

**pholcodine 1 mg/mL oral liquid, 100 mL**

| 4071G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 13.35 | 6.30 | Gold Cross [BI] |
| | | | .. | 18.21 | 6.30 | Duro-Tuss [IA] |

# ▪ ANTIHISTAMINES FOR SYSTEMIC USE

## ANTIHISTAMINES FOR SYSTEMIC USE

*Piperazine derivatives*

### ▪ CETIRIZINE

**cetirizine hydrochloride 10 mg tablet, 30**

| 4175R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 28.06 | 6.30 | [a] Pharmacy Action Cetrelief [GQ] |
| | | | .. | 31.29 | 6.30 | [a] Alzene [AF] |
| | | | .. | 34.09 | 6.30 | Zilarex [SZ] |
| | | | .. | 39.81 | 6.30 | [a] Zyrtec [JT] |

*Other antihistamines for systemic use*

### ▪ FEXOFENADINE

**fexofenadine hydrochloride 120 mg tablet, 30**

| 4238C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 27.88 | 6.30 | [a] Pharmacy Action Fexorelief 120 [GQ] |
| | | | .. | 31.09 | 6.30 | [a] Xergic [AF] |
| | | | .. | 35.69 | 6.30 | [a] Fexal [SZ] |
| | | | .. | 47.30 | 6.30 | [a] Telfast 120 [SW] |

**fexofenadine hydrochloride 60 mg tablet, 20**

| 4237B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | .. | .. | *55.15 | 6.30 | Telfast [SW] |

### ▪ LORATADINE

**loratadine 10 mg tablet, 30**

| 4313B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 30.49 | 6.30 | [a] Pharmacy Action Lorastyne [GQ] |
| | | | .. | 34.19 | 6.30 | [a] Allereze [AF] |
| | | | .. | 43.82 | 6.30 | [a] Lorano [SZ] |
| | | | .. | 46.09 | 6.30 | [a] Claratyne [BN] |

# ▪ SENSORY ORGANS

# ▪ OPHTHALMOLOGICALS

## DECONGESTANTS AND ANTIALLERGICS

*Sympathomimetics used as decongestants*

### ▪ NAPHAZOLINE

**naphazoline hydrochloride 0.1% eye drops, 15 mL**

| 4035J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 18.63 | 6.30 | Albalon Liquifilm [AG] |

### ▪ NAPHAZOLINE + ANTAZOLINE

**naphazoline hydrochloride 0.05% + antazoline phosphate 0.5% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4032F | ‡1 | 1 | .. | 18.38 | 6.30 | Albalon-A [AG] |

*Other antiallergics*

### ▪ LEVOCABASTINE

**levocabastine 0.05% eye drops, 4 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4310W | ‡1 | 1 | .. | 21.37 | 6.30 | Livostin [JT] |

## ▪ OTOLOGICALS

### OTHER OTOLOGICALS

*Indifferent preparations*

### ▪ CARBAMIDE PEROXIDE

**carbamide peroxide 6.5% ear drops, 12 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4176T | ‡1 | .. | .. | 20.57 | 6.30 | Ear Clear for Ear Wax Removal [KY] |

### ▪ DICHLOROBENZENE WITH CHLORBUTOL AND ARACHIS OIL

**DICHLOROBENZENE with CHLORBUTOL and ARACHIS OIL Ear drops, ortho-dichlorobenzene 140 mg per mL, para-dichlorobenzene 20 mg per mL, chlorbutol 50 mg per mL, arachis oil 573 mg per mL, 10 mL, 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4180B | ‡1 | .. | .. | 17.75 | 6.30 | Cerumol [UN] |

### ▪ DOCUSATE

**docusate sodium 0.5% ear drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4199B | ‡1 | .. | .. | 18.09 | 6.30 | Waxsol [HM] |

## ▪ VARIOUS

## ▪ ALL OTHER THERAPEUTIC PRODUCTS

### ALL OTHER THERAPEUTIC PRODUCTS

*Drugs for treatment of hyperkalemia and hyperphosphatemia*

### ▪ SODIUM POLYSTYRENE SULFONATE

**sodium polystyrene sulfonate 999.3 mg/g powder, 454 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4470G | ‡1 | 2 | .. | 69.91 | 6.30 | Resonium-A [SW] |

## ▪ GENERAL NUTRIENTS

### OTHER NUTRIENTS

*Other combinations of nutrients*

### ▪ PROTEIN FORMULA WITH ARGININE, VITAMIN C AND E

**Restricted benefit**

Stage 2 and above pressure injury

**Clinical criteria:**

- The treatment must be for special medical purposes to support healing of pressure injuries.

**protein formula with arginine, vitamin C and E powder for oral liquid, 14 x 9.2 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10850C | 4 | 5 | .. | *128.51 | 6.30 | Arginaid [NT] |

### ▪ PROTEIN FORMULA WITH ARGININE, VITAMIN C, E AND ZINC

**Restricted benefit**

Stage 2 and above pressure injury

**Clinical criteria:**

- The treatment must be for special medical purposes to support healing of pressure injuries.

**protein formula with arginine, vitamin C, E and zinc oral liquid, 27 x 237 mL cartons**

| 10841N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *210.29 | 6.30 | Arginaid Extra [NT] |

# ALL OTHER NON-THERAPEUTIC PRODUCTS

## ALL OTHER NON-THERAPEUTIC PRODUCTS

### LUBRICATING AGENT

**lubricating agent jelly, 100 g**

| 4306P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 14.32 | 6.30 | Lubri-Gel [PP] |

*Other non-therapeutic auxiliary products*

### BANDAGE ABSORBENT WOOL

**bandage absorbent wool 10 cm x 3 m bandage, 1**

| 4653X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 23.18 | 6.30 | Surepress 650948 [CC] |

### BANDAGE CALICO

**bandage calico large triangular bandage, 1**

| 4717G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 17.10 | 6.30 | Handy 36361414 [BV] |

### BANDAGE COMPRESSION

**Note** Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

**BANDAGE-COMPRESSION Bandage, short stretch, 8 cm x 2.6 m, 1**

| 4654Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 5 | .. | .. | *76.90 | 6.30 | Comprilan 01027-00 [BV] |

**bandage compression 10 cm x 3 m high stretch bandage, 1**

| 4748X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 5 | .. | .. | *71.55 | 6.30 | Surepress 650947 [CC] |
| | | | .. | *149.85 | 6.30 | Tensopress 71723-00 [BV] |

### BANDAGE COMPRESSION

**Note** Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

**bandage compression four layer bandage, 1**

| 4598B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 5 | .. | .. | *164.15 | 6.30 | Profore Lite 66050415 [SN] |

**bandage compression four layer bandage, 1**

| 4658E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 5 | .. | .. | *244.65 | 6.30 | Profore 66050016 [SN] |

### BANDAGE COMPRESSION

**Note** Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

**Note** Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

**bandage compression 10 cm x 3.5 m high stretch bandage, 1**

| 4657D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 5 | .. | .. | *76.70 | 6.30 | Setopress 3505 [MH] |

## ▪ BANDAGE COMPRESSION

**Note** Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.
**Note** Bandage can be left in situ for up to 7 days as per manufacturer's instructions.

**Restricted benefit**
Venous ulcer
Treatment Phase: Initial treatment
**Restricted benefit**
Venous ulcer
Treatment Phase: Continuing treatment

**bandage compression two layer bandage, 1**

| 4050E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 42.85 | 6.30 | Coban 2 [MM] |

## ▪ BANDAGE RETENTION COHESIVE HEAVY

**bandage retention cohesive heavy 5 cm x 1.3 m bandage, 1**

| 4811F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *17.69 | 6.30 | Peg 7420 [MM] |

**bandage retention cohesive heavy 10 cm x 1.3 m bandage, 1**

| 4813H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *23.83 | 6.30 | Peg 7423 [MM] |

**bandage retention cohesive heavy 15 cm x 1.3 m bandage, 1**

| 4814J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *30.01 | 6.30 | Peg 7425 [MM] |

**bandage retention cohesive heavy 10 cm x 2 m bandage, 1**

| 4660G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *22.35 | 6.30 | Coban 1584 [MM] |

**bandage retention cohesive heavy 7.5 cm x 1.3 m bandage, 1**

| 4812G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *20.55 | 6.30 | Peg 7422 [MM] |

## ▪ BANDAGE RETENTION COHESIVE LIGHT

**bandage retention cohesive light 6 cm x 2 m bandage, 1**

| 4719J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *19.61 | 6.30 | Handygauze Cohesive 8633 [BV] |

**bandage retention cohesive light 10 cm x 2 m bandage, 1**

| 4662J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *33.47 | 6.30 | Handygauze Cohesive 8635 [BV] |

**bandage retention cohesive light 2.5 cm x 2 m bandage, 2**

| 4718H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 17.23 | 6.30 | Handygauze Cohesive 8631 [BV] |

## ▪ BANDAGE RETENTION COTTON CREPE

**bandage retention cotton crepe 5 cm x 2.3 m bandage, 1**

| 4727T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *20.65 | 6.30 | Telfa 8252F [KE] |
| | | | .. | *23.31 | 6.30 | Tensocrepe 36300501 [BV] |

**bandage retention cotton crepe 10 cm x 2.3 m bandage, 1**

| 4729X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *27.57 | 6.30 | Telfa 8254F [KE] |
| | | | .. | *33.01 | 6.30 | Tensocrepe 36301001 [BV] |

**bandage retention cotton crepe 7.5 cm x 2.3 m bandage, 1**

| 4728W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *24.83 | 6.30 | Telfa 8253F [KE] |

| | | | | | |
|---|---|---|---|---|---|
| .. | *27.87 | 6.30 | Tensocrepe 36307501 [BV] |

## ▪ BANDAGE TUBULAR

**bandage tubular size E (35 cm to 45 cm) straight bandage, 1**

4665M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 18.89 | 6.30 | Elastoplast 2227 [BE] |

**bandage tubular size C (15 cm to 25 cm) straight bandage, 1**

4663K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 18.89 | 6.30 | Elastoplast 2225 [BE] |

**bandage tubular size D (25 cm to 43 cm) straight bandage, 1**

4664L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 18.89 | 6.30 | Elastoplast 2226 [BE] |

## ▪ BANDAGE TUBULAR

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**bandage tubular 6.25 cm x 1 m bandage, 1**

4855M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 18.53 | 6.30 | Tubigrip B 1520 [MH] |

**bandage tubular 8.75 cm x 1 m bandage, 1**

4858Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 18.53 | 6.30 | Tubigrip E 1547 [MH] |

**bandage tubular 7.5 cm x 1 m bandage, 1**

4857P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 18.53 | 6.30 | Tubigrip D 1546 [MH] |

**bandage tubular 10 cm x 1 m bandage, 1**

4859R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 18.53 | 6.30 | Tubigrip F 1548 [MH] |

**bandage tubular 6.75 cm x 1 m bandage, 1**

4856N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 18.53 | 6.30 | Tubigrip C 1545 [MH] |

## ▪ BANDAGE TUBULAR FINGER

**BANDAGE-TUBULAR (FINGER) Complete pack including applicator, 1**

4798M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 20.96 | 6.30 | Tubegauz 0501633 [SS] |

## ▪ BANDAGE TUBULAR LIGHT WEIGHT

**Note** Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

**bandage tubular light weight 10 m medium limb size bandage, 1**

4672X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 28.74 | 6.30 | Tubifast 2436 [MH] |

**bandage tubular light weight 10 m large limb size bandage, 1**

4673Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 29.97 | 6.30 | Tubifast 2438 [MH] |

**bandage tubular light weight 10 m small limb size bandage, 1**

4671W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 25.30 | 6.30 | Tubifast 2434 [MH] |

## ▪ BANDAGE TUBULAR LONG STOCKING

**Note** Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

**bandage tubular long stocking small size bandage, 1**

| 4674B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *37.79 | 6.30 | Tubigrip 1482 [MH] |

**bandage tubular long stocking XX/large size bandage, 1**

| 4675C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *37.81 | 6.30 | Tubigrip 1486 [MH] |

**bandage tubular long stocking large size bandage, 1**

| 4799N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *37.79 | 6.30 | Tubigrip 1484 [MH] |

**bandage tubular long stocking medium size bandage, 1**

| 4797L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *37.79 | 6.30 | Tubigrip 1483 [MH] |

## ▪ BANDAGE TUBULAR SHORT STOCKING

**Note** Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

**bandage tubular short stocking medium C/D size bandage, 1**

| 4815K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *27.57 | 6.30 | Tubigrip 1480 [MH] |

**bandage tubular short stocking small B/C size bandage, 1**

| 4661H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *27.57 | 6.30 | Tubigrip 1479 [MH] |

**bandage tubular short stocking large D/E size bandage, 1**

| 4816L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *27.57 | 6.30 | Tubigrip 1481 [MH] |

## ▪ BANDAGE ZINC PASTE

**Note** Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

**bandage zinc paste 10 cm x 9.1 m bandage, 1**

| 4670T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 3 | .. | *30.53 | 6.30 | Flexidress 650941 [CC] |

## ▪ BANDAGE ZINC PASTE

**Note** Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

**Note** Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

**bandage zinc paste 7.5 cm x 6 m bandage, 1**

| 4669R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 3 | .. | *31.29 | 6.30 | Steripaste 3610 [MH] |

## ▪ BANDAGE ZINC PASTE

**Note** Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

**bandage zinc paste 7.5 cm x 6 m bandage, 1**

| 4750B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 3 | .. | *86.29 | 6.30 | Viscopaste 4948 [SN] |

**bandage zinc paste 80 cm (stockings) bandage, 4**

| 4760M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 3 | .. | 98.90 | 6.30 | ZipZoc 66000747 [SN] |

## ▪ BETAINE + POLYAMINOPROPYL BIGUANIDE

**betaine 0.1% + polyaminopropyl biguanide 0.1% solution, 6 x 40 mL ampoules**

| 2525X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 28.70 | 6.30 | Prontosan Wound Irrigation Solution [BR] |

## ▪ CADEXOMER-IODINE

**Note** Suitable for yellow sloughy infected and malodorous wounds.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**cadexomer-iodine 50% ointment, 4 x 10 g**

| 4932N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 118.06 | 6.30 | Iodosorb Ointment 66051240 [SN] |

**DRESSING with CADEXOMER IODINE Sheets 17 g (10 cm x 8 cm), 2, 1**

| 4937W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 168.09 | 6.30 | Iodosorb 66051360 [SN] |

**cadexomer-iodine 8 cm x 6 cm dressing, 3 x 10 g sheet**

| 4936T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 159.73 | 6.30 | Iodosorb 66051340 [SN] |

**cadexomer-iodine 50% ointment, 2 x 20 g**

| 4933P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 117.00 | 6.30 | Iodosorb Ointment 66051230 [SN] |

**cadexomer-iodine 3 g sterile dusting powder, 7 sachets**

| 4931M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 74.91 | 6.30 | Iodosorb Powder 66051070 [SN] |

**DRESSING with CADEXOMER IODINE Sheets 5 g (6 cm x 4 cm), 5, 1**

| 4935R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 111.81 | 6.30 | Iodosorb 66051330 [SN] |

## ▪ DRESSING ACTIVATED CHARCOAL MALODOROUS WOUND

**dressing activated charcoal malodorous wound 10.5 cm x 10.5 cm dressing, 1**

| 4681J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 10 | .. | .. | *96.95 | 6.30 | Actisorb Plus MAP105 [KI] |

**dressing activated charcoal malodorous wound 15 cm x 20 cm dressing, 5**

| 4743P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 86.95 | 6.30 | CarboFLEX 403204 [CC] |

**dressing activated charcoal malodorous wound 10 cm x 10 cm dressing, 10**

| 4742N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 77.05 | 6.30 | CarboFLEX 403202 [CC] |

## ▪ DRESSING ALGINATE CAVITY WOUND

**Note** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

**DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 1**

4832H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10 | .. | .. | *104.45 | 6.30 | Sorbsan 1411 [UM] |

**DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 5**

1905G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *110.03 | 6.30 | Kaltostat 168117 [CC] |

## ▪ DRESSING ALGINATE CAVITY WOUND

**Note** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**dressing alginate cavity wound 2 g (40 cm) rope, 6 x 2 g**

4682K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *130.45 | 6.30 | Comfeel SeaSorb Filler 3740 [CT] |

## ▪ DRESSING ALGINATE SUPERFICIAL WOUND

**Note** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

**dressing alginate superficial wound 7.5 cm x 12 cm dressing, 10**

4683L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 88.05 | 6.30 | Kaltostat 168212 [CC] |

## ▪ DRESSING ALGINATE SUPERFICIAL WOUND

**Note** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing alginate superficial wound 10 cm x 10 cm dressing, 10**

4700J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 113.67 | 6.30 | Algisite M 66000520 [SN] |

**dressing alginate superficial wound 15 cm x 20 cm dressing, 10**

4691X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 273.44 | 6.30 | Algisite M 66000521 [SN] |

**dressing alginate superficial wound 5 cm x 5 cm dressing, 10**

4699H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 49.57 | 6.30 | Kaltostat 168210 [CC] |
| | | .. | 60.59 | 6.30 | Algisite M 66000519 [SN] |

## ▪ DRESSING ALGINATE SUPERFICIAL WOUND

**Note** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**dressing alginate superficial wound 10 cm x 10 cm dressing, 1**

4831G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10 | 1 | .. | *81.95 | 6.30 | Sorbsan 1410 [UM] |
| | | .. | *87.15 | 6.30 | Comfeel SeaSorb Dressing 3710 [CT] |

**dressing alginate superficial wound 5 cm x 5 cm dressing, 1**

| 4684M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 10 | 1 | .. | *47.05 | 6.30 | Comfeel SeaSorb Dressing 3705 [CT] |

## ▪ DRESSING ALGINATE WITH MANUKA HONEY

**Note** Suitable for yellow sloughy infected and malodorous wounds.

**dressing alginate with manuka honey 10 cm x 10 cm dressing, 5**

| 10849B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 4 | .. | 63.56 | 6.30 | Algivon Plus CR4225 [DJ] |

**dressing alginate with manuka honey 2.5 cm x 20 cm ribbon, 5**

| 10857K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 4 | .. | 114.85 | 6.30 | Algivon Plus Ribbon & Probe CR4231 [DJ] |

## ▪ DRESSING FILM

**dressing film 6 cm x 7 cm dressing, 8**

| 4686P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 19.11 | 6.30 | Nexcare Tegaderm Transparent H1624 [MM] |

**dressing film 10 cm x 12 cm dressing, 4**

| 4687Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 22.59 | 6.30 | Nexcare Tegaderm Transparent H1626 [MM] |

**dressing film 15 cm x 20 cm dressing, 1**

| 4688R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 6 | .. | .. | *32.17 | 6.30 | Tegaderm Transparent 1628 [MM] |

## ▪ DRESSING FILM

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing film 10 cm x 12 cm dressing, 10**

| 4893M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 37.41 | 6.30 | Op-Site Flexigrid 4629 [SN] |

## ▪ DRESSING FILM ISLAND

**dressing film island 9 cm x 10 cm dressing, 1**

| 4690W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 10 | .. | .. | *29.55 | 6.30 | Tegaderm Transparent Island 3586 [MM] |

**dressing film island 5 cm x 7 cm dressing, 1**

| 4689T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 10 | .. | .. | *19.55 | 6.30 | Tegaderm Transparent Island 3582 [MM] |

## ▪ DRESSING FILM ISLAND

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing film island 5 cm x 7.2 cm dressing, 5**

| 4898T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *32.65 | 6.30 | Cutifilm Plus 36361370 [SN] |

**dressing film island 8 cm x 10 cm dressing, 5**

| 4899W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *49.21 | 6.30 | Cutifilm Plus 36361371 [SN] |

## ▪ DRESSING FOAM HEAVY EXUDATE

**Note** This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing foam heavy exudate 10 cm x 10 cm dressing, 10**

| 4795J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 137.01 | 6.30 | Allevyn 66007637 [SN] |

## ▪ DRESSING FOAM MODERATE EXUDATE

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing foam moderate exudate cavity conforming foam, 20 g sachet**

| 4694C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 98.92 | 6.30 | Cavicare 4563 [SN] |

## ▪ DRESSING FOAM MODERATE EXUDATE

**Note** This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing foam moderate exudate 12.5 cm x 12.5 cm dressing, 10**

| 4590N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 141.33 | 6.30 | Allevyn Adhesive 66000044 [SN] |

## ▪ DRESSING FOAM WITH SILICONE

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing foam with silicone 21 cm x 21 cm dressing, 10**

| 10021K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 232.10 | 6.30 | Allevyn Life 66801070 [SN] |

**dressing foam with silicone 12.9 cm x 12.9 cm dressing, 10**

| 10029W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 85.30 | 6.30 | Allevyn Life 66801068 [SN] |

**dressing foam with silicone 15.4 cm x 15.4 cm dressing, 10**

| 10023M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 116.86 | 6.30 | Allevyn Life 66801069 [SN] |

**dressing foam with silicone 10.3 cm x 10.3 cm dressing, 10**

| 10017F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 60.55 | 6.30 | Allevyn Life 66801067 [SN] |

## ▪ DRESSING FOAM WITH SILICONE AND SILVER

**Note** Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

**Authority required**

Wounds

**Clinical criteria:**

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

**dressing foam with silicone and silver 10 cm x 10 cm dressing, 5**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2439J | ‡1 | .. | .. | 104.62 | 6.30 | Mepilex Ag [MH] |

**dressing foam with silicone and silver 10 cm x 10 cm dressing, 5**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2470B | ‡1 | .. | .. | 111.67 | 6.30 | Mepilex Border Ag [MH] |

## ▪ DRESSING FOAM WITH SILICONE HEAVY EXUDATE

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing foam with silicone heavy exudate 7.5 cm x 7.5 cm dressing, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4207K | ‡1 | .. | .. | 57.32 | 6.30 | Allevyn Gentle Border 66800269 [SN] |

**dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4196W | ‡1 | .. | .. | 80.43 | 6.30 | Allevyn Gentle 66800248 [SN] |

**dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4230P | ‡1 | .. | .. | 80.43 | 6.30 | Allevyn Gentle Border 66800270 [SN] |

## ▪ DRESSING FOAM WITH SILICONE HEAVY EXUDATE

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**dressing foam with silicone heavy exudate 7.5 cm x 7.5 cm dressing, 5**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4642H | ‡1 | .. | .. | 32.26 | 6.30 | Mepilex Border 295200 [MH] |

**dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 5**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4643J | ‡1 | .. | .. | 42.85 | 6.30 | Mepilex Border 295300 [MH] |

## ▪ DRESSING FOAM WITH SILICONE LIGHT EXUDATE

**Note** Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

**dressing foam with silicone light exudate 6 cm x 8.5 cm dressing, 5**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4644K | ‡1 | .. | .. | 29.91 | 6.30 | Mepilex Lite 284000 [MH] |

**dressing foam with silicone light exudate 10 cm x 10 cm dressing, 5**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4645L | ‡1 | .. | .. | 38.73 | 6.30 | Mepilex Lite 284100 [MH] |

## ▪ DRESSING FOAM WITH SILICONE MODERATE EXUDATE

**Note** Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

**dressing foam with silicone moderate exudate 10 cm x 10 cm dressing, 5**

| 4626L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 42.85 | 6.30 | Mepilex 294100 [MH] |

## ▪ DRESSING FOAM WITH SILVER

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**Authority required**

Wounds

**Clinical criteria:**

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

**dressing foam with silver 12.5 cm x 12.5 cm dressing, 10**

| 4258D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 267.18 | 6.30 | Allevyn Ag Adhesive 66800078 [SN] |

**dressing foam with silver 12.5 cm x 12.5 cm dressing, 10**

| 4270R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 267.18 | 6.30 | Allevyn Ag Gentle Border 66800462 [SN] |

**dressing foam with silver 10 cm x 10 cm dressing, 10**

| 4255Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 214.69 | 6.30 | Allevyn Ag Adhesive 66800075 [SN] |

**dressing foam with silver 10 cm x 10 cm dressing, 10**

| 4259E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 218.86 | 6.30 | Allevyn Ag Non-Adhesive 66800086 [SN] |

**dressing foam with silver 10 cm x 10 cm dressing, 10**

| 4266M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 214.69 | 6.30 | Allevyn Ag Gentle Border 66800461 [SN] |

**dressing foam with silver 7.5 cm x 7.5 cm dressing, 10**

| 4252T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 145.29 | 6.30 | Allevyn Ag Adhesive 66800073 [SN] |

**dressing foam with silver 7.5 cm x 7.5 cm dressing, 10**

| 4263J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 145.29 | 6.30 | Allevyn Ag Gentle Border 66800460 [SN] |

## ▪ DRESSING GAUZE ABSORBENT

**dressing gauze absorbent 10 cm x 10 cm pad, 100**

| 4708T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 32.42 | 6.30 | Handy 71117-06 [BV] |

**dressing gauze absorbent 5 cm x 5 cm pad, 100**

| 4707R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 18.69 | 6.30 | Handy 71117-05 [BV] |

## ▪ DRESSING GAUZE EYE

**dressing gauze eye pad, 12 pads**

| 4768Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 16.66 | 6.30 | Curity 4112 [KE] |

## ▪ DRESSING GAUZE PARAFFIN

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler

cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing gauze paraffin 10 cm x 10 cm dressing, 10**

| 4759L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 25.50 | 6.30 | Jelonet 7404 [SN] |

## ▪ DRESSING GAUZE PARAFFIN WITH CHLORHEXIDINE ACETATE

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing gauze paraffin with chlorhexidine acetate 10 cm x 10 cm dressing, 10**

| 4845B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 31.72 | 6.30 | Bactigras 7457 [SN] |

## ▪ DRESSING HYDROACTIVE DEBRIDEMENT

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

**DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 4 cm, 10, 1**

| 4949L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 82.42 | 6.30 | TenderWet 24 Active 609210 [HR] |

**DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 5.5 cm, 10, 1**

| 4948K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 84.28 | 6.30 | TenderWet Active Cavity 609272 [HR] |

**DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 7.5 cm x 7.5 cm, 10, 1**

| 4950M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 110.02 | 6.30 | TenderWet 24 Active 609213 [HR] |

## ▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM

**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 10 cm x 10 cm (foam alternative) dressing, 10**

| 4692Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 55.07 | 6.30 | CombiDERM 651031 [CC] |

**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 11 cm x 11 cm dressing: island, 10 dressings**

| 4695D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 106.38 | 6.30 | Tielle MTL101E [KI] |

**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 18 cm (foam alternative) dressing, 5**

| 4693B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 70.45 | 6.30 | CombiDERM 651027 [CC] |

**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm dressing: island, 5 dressings**

| 4696E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 128.74 | 6.30 | Tielle MTL103 [KI] |

## ▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 10 cm x 10 cm waterproof pad, 10**

| 4927H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 85.19 | 6.30 | Biatain Non-adhesive 3410 [CT] |

**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 12 cm x 12 cm waterproof pad, 10**

| 4929K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 93.39 | 6.30 | Biatain Adhesive 3420 [CT] |

**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 15 cm waterproof pad, 5**

| 4928J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 83.84 | 6.30 | Biatain Non-adhesive 3413 [CT] |

**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm waterproof pad, 5**

| 4930L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 90.54 | 6.30 | Biatain Adhesive 3423 [CT] |

## ▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND LIGHT EXUDATE

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing hydroactive superficial wound light exudate 5 cm x 6 cm dressing, 10**

| 4905E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 66.34 | 6.30 | Allevyn Thin 66047576 [SN] |

**dressing hydroactive superficial wound light exudate 10 cm x 10 cm dressing, 5**

| 4906F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 1 | .. | *117.85 | 6.30 | Allevyn Thin 66047578 [SN] |

## ▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND MODERATE EXUDATE

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing hydroactive superficial wound moderate exudate 5 cm x 6 cm dressing, 10**

| 4885D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 56.44 | 6.30 | Cutinova Hydro 66047441 [SN] |

**dressing hydroactive superficial wound moderate exudate 10 cm x 10 cm dressing, 5**

| 4886E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 1 | .. | *92.49 | 6.30 | Cutinova Hydro 66047443 [SN] |

## ▪ DRESSING HYDROCOLLOID CAVITY WOUND

**Note** This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

**dressing hydrocolloid cavity wound paste, 30 g**

| 4896Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 10 | .. | .. | *137.15 | 6.30 | DuoDERM Paste H7930 [CC] |

## ▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

**dressing hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10**

| 4907G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 70.45 | 6.30 | DuoDERM Extra Thin H7955 [CC] |

## ▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**dressing hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10**

| 4924E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 68.69 | 6.30 | Comfeel Plus Transparent 3533 [CT] |

**dressing hydrocolloid superficial wound light exudate 9 cm x 14 cm dressing, 10**

| 4889H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 82.09 | 6.30 | Comfeel Plus Transparent 3536 [CT] |

**dressing hydrocolloid superficial wound light exudate 5 cm x 7 cm dressing, 10**

| 4888G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 41.89 | 6.30 | Comfeel Plus Transparent 3530 [CT] |

## ▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

**dressing hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10**

| 4947J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 48.32 | 6.30 | Hydrocoll Thin 900758 [HR] |

## ▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

**Note** This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

**dressing hydrocolloid superficial wound moderate exudate 20 cm x 20 cm dressing, 5**

| 4920Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 1 | .. | *209.61 | 6.30 | DuoDERM CGF H7662 [CC] |

**dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 5**

| 4897R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 1 | .. | *79.25 | 6.30 | DuoDERM CGF H7660 [CC] |

## ▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

**Note** This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 10**

| 4921B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 93.46 | 6.30 | Replicare Ultra 66000434 [SN] |

## ▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

**Note** This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

**dressing hydrocolloid superficial wound moderate exudate 15 cm x 15 cm dressing, 10**

| 4946H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 86.99 | 6.30 | Hydrocoll 900936 [HR] |

**dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 10**

| 4945G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 48.32 | 6.30 | Hydrocoll 900744 [HR] |

## ▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

**Note** This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**dressing hydrocolloid superficial wound moderate exudate 7cm (butterfly shape) dressing, 1**

| 4678F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 5 | .. | .. | *55.35 | 6.30 | Comfeel Plus Pressure Relieving 3350 [CT] |

**dressing hydrocolloid superficial wound moderate exudate 10cm (round) dressing, 1**

| 4679G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 5 | .. | .. | *59.45 | 6.30 | Comfeel Plus Pressure Relieving 3353 [CT] |

**DRESSING-HYDROCOLLOID (SUPERFICIAL WOUND-MODERATE EXUDATE) Dressings with alginate 10 cm x 10 cm, 10, 1**

| 4923D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 79.80 | 6.30 | Comfeel Plus Ulcer Dressing 3110 [CT] |

## ▪ DRESSING HYDROFIBRE ALTERNATE TO ALGINATES

**dressing hydrofibre alternate to alginates 10 cm x 10 cm dressing, 10**

| 10837J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 120.20 | 6.30 | Aquacel Foam Non-Adhesive [CC] |

**dressing hydrofibre alternate to alginates 10 cm x 10 cm dressing, 10**

| 2797F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 97.05 | 6.30 | Aquacel Extra 420672 [CC] |

**dressing hydrofibre alternate to alginates 2 g (30 cm) rope, 5 x 2 g**

| 4698G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 81.35 | 6.30 | Aquacel 403770 [CC] |

**dressing hydrofibre alternate to alginates 12.5 cm x 12.5 cm dressing, 10**

| 10832D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 116.73 | 6.30 | Aquacel Foam Adhesive [CC] |

**dressing hydrofibre alternate to alginates 15 cm x 15 cm dressing, 5**

| 2803M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 1 | .. | *195.51 | 6.30 | Aquacel Extra 420673 [CC] |

## ▪ DRESSING HYDROFIBRE GELLING FIBRE

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing hydrofibre gelling fibre 2 cm x 45 cm rope, 5**

| 2462N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 87.24 | 6.30 | Durafiber 66800563 [SN] |

**dressing hydrofibre gelling fibre 10 cm x 10 cm dressing, 10**

| 2486W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 103.62 | 6.30 | Durafiber 66800560 [SN] |

**dressing hydrofibre gelling fibre 15 cm x 15 cm dressing, 5**

| 2445Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡2 | 1 | .. | *211.59 | 6.30 | Durafiber 66800561 [SN] |

## ▪ DRESSING HYDROFIBRE WITH SILVER

**Authority required**

Wounds

**Clinical criteria:**

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

### dressing hydrofibre with silver 10 cm x 10 cm dressing, 10

| 10097K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 250.75 | 6.30 | Aquacel Ag 403708 [CC] |

### dressing hydrofibre with silver 2 cm x 45 cm rope, 5

| 10105W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 211.81 | 6.30 | Aquacel Ag 403771 [CC] |

### dressing hydrofibre with silver 15 cm x 15 cm dressing, 5

| 10098L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 268.39 | 6.30 | Aquacel Ag 403710 [CC] |

## ▪ DRESSING HYDROGEL

### dressing hydrogel 10 cm x 10 cm dressing, 20

| 2471C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 108.93 | 6.30 | Sorbact Absorption Dressing S98222 [QL] |

## ▪ DRESSING HYDROGEL AMORPHOUS

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

### dressing hydrogel amorphous gel, 50 g

| 4914P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 3 | .. | *34.30 | 6.30 | Solugel 10336 [JJ] |

### dressing hydrogel amorphous gel, 3 x 30 g

| 4913N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 1 | .. | *93.52 | 6.30 | DuoDERM Gel H7987 [CC] |

## ▪ DRESSING HYDROGEL AMORPHOUS

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

### dressing hydrogel amorphous gel, 10 x 15 g

| 4912M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 63.87 | 6.30 | DuoDERM Gel H7990 [CC] |
| | | | .. | 70.79 | 6.30 | Comfeel Purilon Gel 3900 [CT] |

## ▪ DRESSING HYDROGEL AMORPHOUS

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

### dressing hydrogel amorphous gel, 50 g

| 4599C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 3 | .. | *34.75 | 6.30 | SoloSite Gel 36361338 [SN] |

**dressing hydrogel amorphous gel, 25 g**

| 4894N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | 3 | .. | *73.31 | 6.30 | Intrasite Gel 7313 [SN] |

## ▪ DRESSING HYDROGEL FOAM

**dressing hydrogel foam 10 cm x 10 cm dressing, 10**

| 2533H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 77.48 | 6.30 | Sorbact Foam Dressing S98310 [QL] |

## ▪ DRESSING HYDROGEL RIBBON

**dressing hydrogel ribbon 5 cm x 200 cm dressing, 10**

| 2529D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 108.93 | 6.30 | Sorbact Ribbon Gauze S98120 [QL] |

**dressing hydrogel ribbon 1 cm x 50 cm dressing, 20**

| 2512F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 112.43 | 6.30 | Sorbact Ribbon Gauze S98118 [QL] |

## ▪ DRESSING HYDROGEL SHEET

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

**dressing hydrogel sheet 9.5 cm x 10.2 cm dressing, 5**

| 4911L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *80.89 | 6.30 | Nu-Gel 2497 [KI] |

## ▪ DRESSING HYDROGEL SHEET

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

**dressing hydrogel sheet 10 cm x 10 cm dressing, 5**

| 4806Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *53.45 | 6.30 | Hydrosorb 900854 [HR] |

## ▪ DRESSING NON ADHERENT

**Note** Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

**DRESSING SELF ADHESIVE NON-ADHERENT DRY ABSORBENT Dressings, non-woven, with silicone 5 cm x 7.5 cm, 10, 1**

| 4243H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 63.09 | 6.30 | Mepitel 290510 [MH] |

**DRESSING SELF ADHESIVE NON-ADHERENT DRY ABSORBENT Dressings, non-woven, with silicone 7.5 cm x 10 cm, 10, 1**

| 4244J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 103.09 | 6.30 | Mepitel 290710 [MH] |

## ▪ DRESSING NON ADHERENT

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

**dressing non adherent 7.5 cm x 10 cm dressing, 10**

| 4944F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 18.76 | 6.30 | Atrauman 499513 [HR] |

## ▪ DRESSING NON ADHERENT

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

### dressing non adherent 10 cm x 10 cm dressing, 5

| 4862X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *28.93 | 6.30 | Cutilin Non-Stick Wound Pad 36361375 [SN] |

### dressing non adherent 10 cm x 10 cm dressing, 10

| 4861W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 39.21 | 6.30 | Melolin 66974933 [SN] |

### dressing non adherent 5 cm x 5 cm dressing, 5

| 4819P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *19.89 | 6.30 | Cutilin Non-Stick Wound Pad 36361374 [SN] |

### dressing non adherent 5 cm x 5 cm dressing, 5

| 4860T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *21.13 | 6.30 | Melolin 36361357 [SN] |

## ▪ DRESSING TULLE NON GAUZE PARAFFIN

### dressing tulle non gauze paraffin 7.6 cm x 7.6 cm dressing, 1

| 4909J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 10 | 1 | .. | *19.15 | 6.30 | Adaptic 2012 [KI] |

## ▪ DRESSING WITH SILVER

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**Authority required**

Wounds

**Clinical criteria:**

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

### dressing with silver 10 cm x 10 cm hydroactive dressing, 5

| 4646M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 165.14 | 6.30 | Biatain Ag 9622 [CT] |

### dressing with silver 12.5 cm x 12.5 cm hydroactive dressing, 5

| 4647N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 179.15 | 6.30 | Biatain Ag 9632 [CT] |

## ▪ DRESSING WITH SILVER

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

**Authority required**

Wounds

**Clinical criteria:**

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

### dressing with silver 10 cm x 10 cm tulle dressing, 3

| 4648P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 43.95 | 6.30 | Atrauman Ag 499572 [HR] |

## ▪ GAUZE AND COTTON TISSUE COMBINE ROLL

**gauze and cotton tissue combine roll 10 cm x 10 m roll: wrapped pack, 1 pack**

| 4761N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 20.47 | 6.30 | JJ 12010 [JJ] |

**gauze and cotton tissue combine roll 9 cm x 10 m roll: wrapped pack, 1 pack**

| 4767X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 15.78 | 6.30 | BSN 2902165 [BV] |

## ▪ POVIDONE-IODINE

**povidone-iodine 9.5 cm x 9.5 cm dressing, 25**

| 10847X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 77.64 | 6.30 | Inadine [KI] |

## ▪ SODIUM CHLORIDE + HYPOCHLOROUS ACID + SODIUM HYPOCHLORITE

**sodium chloride 0.022% + hypochlorous acid 0.004% + sodium hypochlorite 0.004% irrigation solution, 250 mL**

| 11134B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 3 | .. | 30.44 | 6.30 | Microdacyn [TF] |

## ▪ TAPE NON WOVEN RETENTION POLYACRYLATE

**tape non woven retention polyacrylate 2.5 cm x 9.1 m tape, 1 roll**

| 4915Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 16.70 | 6.30 | Medipore 2961 [MM] |

## ▪ TAPE NON WOVEN RETENTION POLYACRYLATE

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**tape non woven retention polyacrylate 2.5 cm x 10 m tape, 1 roll**

| 4917T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 15.11 | 6.30 | Mefix 310250 [MH] |

## ▪ TAPE PLASTER ADHESIVE ELASTIC

**tape plaster adhesive elastic 7.5 cm x 2.5 m tape, 1 roll**

| 4782Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 27.24 | 6.30 | Leukoplast 01073-00 [BV] |

**tape plaster adhesive elastic 5 cm x 2.5 m tape, 1 roll**

| 4781P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 23.56 | 6.30 | Leukoplast 01072-00 [BV] |

**tape plaster adhesive elastic 2.5 cm x 2.5 m tape, 1 roll**

| 4780N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 17.62 | 6.30 | Leukoplast 01071-00 [BV] |

## ▪ TAPE PLASTER ADHESIVE HYPOALLERGENIC

**tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll**

| 4783R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 15.03 | 6.30 | Leukopor 2471 [BV] |

**tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll**

| 4785W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 15.32 | 6.30 | Leukosilk 1021 [BV] |

**tape plaster adhesive hypoallergenic 1.9 cm x 7.3 m dispenser tape, 1 roll**

| 4849F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 15.12 | 6.30 | Nexcare Gentle Paper First Aid Tape 789 [MM] |

**tape plaster adhesive hypoallergenic 1.9 cm x 5.4 m dispenser tape, 1 roll**

| 4848E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 15.12 | 6.30 | Nexcare Durable Cloth First Aid Tape 799 [MM] |

**tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll**

| 4788B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 20.47 | 6.30 | Leukoflex 1124 [BV] |

**tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll**

| 4789C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 21.79 | 6.30 | Leukosilk 1024 [BV] |

**tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll**

| 4790D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 20.96 | 6.30 | Leukopor 2474 [BV] |

**tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll**

| 4787Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 17.97 | 6.30 | Leukosilk 1022 [BV] |

**tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll**

| 4794H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 17.44 | 6.30 | Leukopor 2472 [BV] |

## ▪ TAPE PLASTER ADHESIVE WITH SILICONE

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**tape plaster adhesive with silicone 4 cm x 1.5 m tape, 1 roll**

| 4240E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 24.09 | 6.30 | Mepitac 298400 [MH] |

**tape plaster adhesive with silicone 2 cm x 3 m tape, 1 roll**

| 4239D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 24.09 | 6.30 | Mepitac 298300 [MH] |

# Extemporaneously Prepared Benefits

# Drug Tariff

| Drug | Standard | Recovery Prices | | | |
|---|---|---|---|---|---|
| | | 0.1 g/mL $ | 1 g/mL $ | 10 g/mL $ | 100 g/mL $ |
| Acacia Mucilage (by weight) | APF 15 | 0.02 | 0.12 | 0.96 | 8.49 |
| Acacia, powdered | BP | 0.03 | 0.22 | 1.79 | 15.91 |
| Acetic Acid (33 per cent) | BP | 0.01 | 0.06 | 0.46 | 4.07 |
| Acetic Acid (6 per cent) | BP | 0.01 | 0.02 | 0.15 | 1.31 |
| Acetic Acid Glacial BP | BP | 0.02 | 0.14 | 1.09 | 9.69 |
| Acetone (use as additive only) | BP | 0.03 | 0.20 | 1.63 | 14.50 |
| Alum | BP | 0.01 | 0.07 | 0.59 | 5.25 |
| Aluminium Acetate Solution | BP | 0.02 | 0.17 | 1.38 | 12.27 |
| Anise Oil BP | BP | 0.18 | 1.44 | 11.52 | 102.44 |
| Anise Water Concentrated 1 in 40 | BP | 0.01 | 0.07 | 0.57 | 5.03 |
| Aqueous Cream (for use only as a base combined with active ingredients) | APF | 0.01 | 0.03 | 0.24 | 2.10 |
| Ascorbic Acid (for use only as an ingredient of ferrous sulfate mixtures) | BP | 0.37 | 2.99 | 23.94 | 212.76 |
| Aspirin | BP | 0.14 | 1.15 | 9.22 | 81.94 |
| Belladonna Tincture | BP | 0.10 | 0.81 | 6.44 | 57.28 |
| Benzocaine | BP | 0.12 | 0.97 | 7.76 | 68.94 |
| Benzoic Acid | BP | 0.06 | 0.48 | 3.80 | 33.80 |
| Benzoic Acid Compound Ointment | APF | 0.02 | 0.16 | 1.26 | 11.22 |
| Benzoic Acid Solution | BP | 0.02 | 0.14 | 1.09 | 9.73 |
| Benzoin Compound Tincture | BP | 0.05 | 0.43 | 3.47 | 30.81 |
| Boric Acid (use as additive only) | BP | 0.02 | 0.19 | 1.55 | 13.79 |
| Boric Acid, Olive Oil and Zinc Oxide Ointment | QHF | 0.02 | 0.14 | 1.09 | 9.67 |
| Calcium Hydroxide | BP | 0.10 | 0.83 | 6.64 | 59.00 |
| Calcium Hydroxide Solution | BP | 0.01 | 0.02 | 0.17 | 1.52 |
| Castor Oil (use as additive only) | BP | 0.02 | 0.18 | 1.41 | 12.50 |
| Cetomacrogol Aqueous Cream (for use only as a base combined with active ingredients) | APF | 0.01 | 0.04 | 0.28 | 2.48 |
| Cetrimide Aqueous Cream (for use only as a base combined with active ingredients) | APF | 0.02 | 0.17 | 1.37 | 12.21 |
| Chlorhexidine Acetate (use as additive only) | BP | 0.63 | 5.03 | 40.21 | 357.42 |
| Chlorhexidine Aqueous Cream (for use only as a base combined with active ingredients) | APF | 0.03 | 0.24 | 1.95 | 17.36 |
| Chloroform (use as additive only) | BP | 0.09 | 0.72 | 5.77 | 51.29 |
| Chloroform Spirit | BP | 0.01 | 0.08 | 0.67 | 5.94 |
| Chloroform Water Concentrated 1 in 40 | APF 15 | 0.01 | 0.11 | 0.84 | 7.45 |
| Citric Acid Monohydrate | BP | 0.04 | 0.29 | 2.28 | 20.25 |
| Coal Tar | BP | 0.28 | 2.21 | 17.70 | 157.34 |
| Coal Tar Solution | BP | 0.02 | 0.16 | 1.25 | 11.15 |
| Cocaine Hydrochloride | BP | 5.41 | 43.26 | 346.09 | 3076.38 |
| Coconut Oil | BP | 0.01 | 0.05 | 0.42 | 3.73 |
| Codeine Linctus | APF | 0.01 | 0.10 | 0.79 | 7.03 |
| Codeine Phosphate (may only be prescribed in linctuses, mixtures or mixtures for children) | BP | 3.82 | 30.58 | 244.67 | 2174.84 |
| Collodion Flexible | BP | 0.19 | 1.55 | 12.37 | 109.92 |
| Dithranol | BP | 4.31 | 34.48 | 275.84 | 2451.94 |
| Emulsifying Ointment (for use only as a base combined with active ingredients) | BP | 0.01 | 0.09 | 0.71 | 6.27 |
| Ephedrine Hydrochloride (may only be prescribed in nasal instillations) | BP | 2.05 | 16.43 | 131.45 | 1168.43 |

| Drug | Standard | Recovery Prices | | | |
|---|---|---|---|---|---|
| | | 0.1 g/mL $ | 1 g/mL $ | 10 g/mL $ | 100 g/mL $ |
| Ethanol (90 per cent) (use as additive only) | BP | 0.01 | 0.04 | 0.28 | 2.45 |
| Ethanol (96 per cent) (use as additive only) | BP | 0.01 | 0.04 | 0.35 | 3.10 |
| Ether Solvent (use as additive only) | BP | 0.25 | 1.97 | 15.73 | 139.82 |
| Eucalyptus Oil (use as additive only) | BP | 0.02 | 0.18 | 1.42 | 12.64 |
| Ferrous Sulfate | BP | 0.04 | 0.29 | 2.32 | 20.59 |
| Formaldehyde Solution | BP | 0.07 | 0.53 | 4.26 | 37.86 |
| Gentian Alkaline Mixture | APF | 0.01 | 0.09 | 0.68 | 6.00 |
| Glycerol | BP | 0.02 | 0.12 | 0.98 | 8.72 |
| Honey Purified (use as additive only) | BP 1993 | 0.01 | 0.03 | 0.27 | 2.44 |
| Hydroxybenzoate Compound Solution | APF | 0.07 | 0.59 | 4.73 | 42.08 |
| Iodine | BP | 0.37 | 2.98 | 23.85 | 211.97 |
| Iodine Alcoholic Solution | BP | 0.04 | 0.28 | 2.26 | 20.11 |
| Iodine Aqueous Oral Solution | BP | 0.03 | 0.26 | 2.11 | 18.72 |
| Kaolin Mixture | BPC 1968 | 0.03 | 0.21 | 1.71 | 15.19 |
| Kaolin and Opium Mixture | APF 14 | 0.01 | 0.10 | 0.82 | 7.27 |
| Lactic Acid | BP | 0.36 | 2.87 | 22.94 | 203.95 |
| Lavender Spike Oil | BPC 1968 | 0.13 | 1.04 | 8.32 | 73.91 |
| Liquorice Liquid Extract | BP | 0.03 | 0.23 | 1.84 | 16.37 |
| Magnesium Carbonate Light | BP | 0.05 | 0.37 | 2.92 | 25.99 |
| Magnesium Sulfate (may only be prescribed for other than oral use) | BP | 0.01 | 0.03 | 0.24 | 2.10 |
| Magnesium Trisilicate | BP | 0.05 | 0.36 | 2.91 | 25.82 |
| Menthol, Racemic or Levomenthol | BP | 0.25 | 2.02 | 16.19 | 143.87 |
| Methyl Hydroxybenzoate | BP | 0.41 | 3.28 | 26.22 | 233.03 |
| Methyl Hydroxybenzoate Solution | APF | 0.04 | 0.35 | 2.80 | 24.87 |
| Methylated Industrial Spirit (use as additive only) | BP | 0.01 | 0.01 | 0.08 | 0.73 |
| Olive Oil (use as additive only) | BP | 0.02 | 0.14 | 1.08 | 9.62 |
| Paraffin Hard | BP | 0.05 | 0.41 | 3.29 | 29.28 |
| Paraffin Light Liquid | BP | 0.02 | 0.17 | 1.39 | 12.32 |
| Paraffin Liquid (use as additive only) | BP | 0.01 | 0.06 | 0.51 | 4.56 |
| Paraffin Soft White | BP | 0.01 | 0.05 | 0.42 | 3.71 |
| Paraffin Soft Yellow | BP | 0.01 | 0.05 | 0.42 | 3.75 |
| Peppermint Oil (use as additive only) | BP | 0.07 | 0.57 | 4.55 | 40.44 |
| Peppermint Water Concentrated 1 in 40 (use as additive only) | APF 16 | 0.04 | 0.34 | 2.72 | 24.17 |
| Phenobarbitone Sodium (may only be prescribed for the treatment of epilepsy) | BP | 9.37 | 74.92 | 599.36 | 5327.61 |
| Phenol Liquefied (not available for ear drops) | BP | 0.13 | 1.02 | 8.17 | 72.64 |
| Podophyllum Resin | BP | 3.78 | 30.25 | 242.03 | 2151.34 |
| Potassium Citrate | BP | 0.02 | 0.19 | 1.53 | 13.64 |
| Potassium Iodide | BP | 0.14 | 1.11 | 8.88 | 78.94 |
| Potassium Permanganate | BP | 0.04 | 0.31 | 2.44 | 21.65 |
| Propyl Hydroxybenzoate | BP | 0.42 | 3.35 | 26.78 | 238.01 |
| Propylene Glycol | BP | 0.02 | 0.12 | 0.95 | 8.48 |
| Red Syrup | APF 15 | 0.02 | 0.13 | 1.04 | 9.23 |
| Resorcinol | BP | 0.42 | 3.32 | 26.54 | 235.88 |
| Salicylic Acid | BP | 0.05 | 0.40 | 3.18 | 28.25 |
| Salicylic Acid Ointment | APF | 0.02 | 0.17 | 1.38 | 12.23 |
| Salicylic Acid Ointment | BP | 0.02 | 0.17 | 1.38 | 12.23 |
| Simple Ointment (white) (for use only as a base combined with active ingredients) | BP | 0.02 | 0.14 | 1.11 | 9.88 |
| Simple Ointment (yellow) (for use only as a base combined with active ingredients) | BP | 0.02 | 0.14 | 1.11 | 9.88 |
| Sodium Bicarbonate | BP | 0.04 | 0.28 | 2.24 | 19.91 |
| Sodium Chloride | BP | 0.02 | 0.17 | 1.34 | 11.88 |
| Sodium Chloride Solution | BP | 0.01 | 0.01 | 0.09 | 0.84 |
| Sodium Citrate | BP | 0.04 | 0.28 | 2.23 | 19.81 |
| Sodium Thiosulfate (use as additive only) | BP | 0.04 | 0.34 | 2.74 | 24.37 |
| Starch | BP | 0.02 | 0.19 | 1.55 | 13.79 |
| Sulfur Ointment (for use only as a base combined with active ingredients) | BP 1980 | 0.02 | 0.15 | 1.21 | 10.75 |
| Sulfur Precipitated | BP 1980 | 0.03 | 0.23 | 1.86 | 16.49 |
| Syrup | BP | 0.01 | 0.05 | 0.42 | 3.71 |
| Talc Purified, sterilised | BP | 0.06 | 0.46 | 3.71 | 32.94 |
| Thymol | BP | 0.46 | 3.71 | 29.66 | 263.61 |
| Thymol Compound Mouth Wash | APF 15 | 0.01 | 0.11 | 0.89 | 7.91 |

| Drug | Standard | Recovery Prices | | | |
|---|---|---|---|---|---|
| | | 0.1 g/mL $ | 1 g/mL $ | 10 g/mL $ | 100 g/mL $ |
| Tragacanth Compound Powder | BP 1980 | 0.07 | 0.57 | 4.58 | 40.73 |
| Tragacanth Mucilage | APF 13 | 0.01 | 0.07 | 0.58 | 5.14 |
| Tragacanth Mucilage | BPC 1973 | 0.01 | 0.06 | 0.51 | 4.56 |
| Tragacanth, powdered | BP | 0.36 | 2.84 | 22.72 | 201.94 |
| Trichloroacetic Acid | BP 1980 | 0.33 | 2.65 | 21.23 | 188.68 |
| Triethanolamine | BP | 0.12 | 0.96 | 7.68 | 68.28 |
| Water For Injections, sterilised (b) (extemporaneously prepared eye drops and eye lotions) | BP | | | | |
| Water Purified | BP | 0.01 | 0.01 | 0.08 | 0.69 |
| Wool Alcohols Ointment (white) (for use only as a base combined with active ingredients) | BP | 0.02 | 0.17 | 1.33 | 11.86 |
| Wool Alcohols Ointment (yellow) (for use only as a base combined with active ingredients) | BP | 0.02 | 0.19 | 1.48 | 13.18 |
| Wool Fat | BP | 0.02 | 0.12 | 0.97 | 8.63 |
| Wool Fat Hydrous | BP | 0.03 | 0.25 | 2.03 | 18.01 |
| Zinc Compound Paste | BP | 0.05 | 0.40 | 3.17 | 28.17 |
| Zinc Cream (for use only as a base combined with active ingredients) | BP | 0.01 | 0.08 | 0.61 | 5.39 |
| Zinc Oxide | BP | 0.03 | 0.21 | 1.66 | 14.79 |
| Zinc Sulfate | BP | 0.04 | 0.28 | 2.21 | 19.63 |
| Zinc and Salicylic Acid Paste | BP | 0.04 | 0.32 | 2.53 | 22.47 |

# Container Prices

| Type | Container | Price $ |
|---|---|---|
| Dispensing Bottles | 25mL | 0.64 |
| Dispensing Bottles | 50mL | 0.53 |
| Dispensing Bottles | 100mL | 0.87 |
| Dispensing Bottles | 200mL | 1.03 |
| Dispensing Bottles | 500mL | 1.28 |
| Poison Bottles | 25mL | 0.67 |
| Poison Bottles | 50mL | 0.54 |
| Poison Bottles | 100mL | 0.79 |
| Poison Bottles | 200mL | 1.02 |
| Poison Bottles | 500mL | 1.69 |
| Dropper Containers (Glass) | 15mL | 1.21 |
| Dropper Containers (Polythene) | 15mL | 0.98 |
| | 150ml | 0.83 |
| Screw Cap Jars | 25g | 0.90 |
| Screw Cap Jars | 50g | 0.96 |
| Screw Cap Jars | 100g | 0.99 |
| Screw Cap Jars | 200g | 0.85 |
| Screw Cap Jars | 500g | 2.19 |
| | 25ml | 0.41 |

# Standard Formula Preparations

| Code | Item | Reference | DPMQ $ | MRVSN $ |
|---|---|---|---|---|
| | **Creams** | | | |
| | **(Maximum Quantity 100 g and 1 Repeat)** | | | |
| 7502W | Salicylic Acid and Sulfur Aqueous | APF | 13.47 | 15.04 |
| | **Dusting Powders** | | | |
| | **(Maximum Quantity 100 g and 1 Repeat)** | | | |
| 7458M | Zinc, Starch and Talc | APF 15 & BPC 1973 | 36.61 | 38.18 |
| | **Ear Drops** | | | |
| | **(Maximum Quantity 15 ml and 2 Repeats)** | | | |
| 7643G | Aluminium Acetate | BP | 12.24 | 13.81 |
| 7642F | Aluminium Acetate | APF | 11.47 | 13.04 |
| 7314Y | Sodium Bicarbonate | APF & BP | 11.01 | 12.58 |
| 7313X | Spirit | APF | 10.44 | 12.01 |
| | **Inhalations** | | | |
| | **(Maximum Quantity 50 ml and 1 Repeat)** | | | |
| 7484X | Benzoin and Menthol | APF | 29.08 | 30.65 |
| 7308P | Menthol | APF | 13.13 | 14.70 |
| 7310R | Menthol and Eucalyptus | BP1980 | 14.27 | 15.84 |
| | **Linctuses containing Codeine Phosphate** | | | |
| | **(Maximum Quantity 100 ml and 0 Repeat)** | | | |
| 7530H | Codeine | APF | 17.09 | 18.66 |
| | **Lotions** | | | |
| | **(Maximum Quantity 200 ml and 2 Repeats)** | | | |
| 7709R | Aluminium Acetate Aqueous | APF | 12.90 | 14.47 |
| | **Mixtures, Other** | | | |
| | **(Maximum Quantity 200 ml and 4 Repeats)** | | | |
| 7604F | Gentian Alkaline | APF | 22.22 | 23.79 |
| 7348R | Kaolin | BPC 1968 | 40.59 | 38.80 |
| 7301G | Kaolin and Opium | APF 14 | 24.76 | 26.33 |
| 7342K | Magnesium Trisilicate | BPC 1968 | 21.34 | 22.91 |
| 7343L | Magnesium Trisilicate and Belladonna | BPC 1968 | 27.63 | 29.20 |
| | **Mouth Washes** | | | |
| | **(Maximum Quantity 200 ml and 1 Repeat)** | | | |
| 7457L | Thymol Compound | APF 15 | 26.03 | 27.60 |
| | **Ointments, Waxes** | | | |
| | **(Maximum Quantity 100 g and 1 Repeat)** | | | |
| 7914M | Benzoic Acid Compound | APF & BP | 21.40 | 22.97 |
| 7902X | Boric Acid, Olive Oil and Zinc Oxide | QHF | 19.85 | 21.42 |
| 7926E | Salicylic Acid | APF | 22.41 | 23.98 |
| 7928G | Salicylic Acid (extemporaneous formula) | BP | 22.41 | 23.98 |
| | **Paints** | | | |
| | **(Maximum Quantity 25 ml and 1 Repeat)** | | | |
| 7567G | Podophyllin Compound | APF 16 & BP | 131.97 | 38.80 |
| 7568H | Salicylic Acid | APF | 41.77 | 38.80 |
| | **Pastes, Other** | | | |
| | **(Maximum Quantity 100 g and 1 Repeat)** | | | |
| 7558T | Zinc | APF & BP | 38.35 | 38.80 |
| | **Powders for Internal Use** | | | |
| | **(Maximum Quantity 100 g and 2 Repeats)** | | | |
| 7545D | Magnesium Trisilicate | BP | 35.86 | 37.43 |

# Codes, Maximum Quantities, and Number of Repeats for Extemporaneously Prepared Benefits

| Code | Preparation | Maximum Quantity | Number of Repeats |
|---|---|---|---|
| 13Q | Creams | 100 g | 1 |
| 48M | Dusting Powders | 100 g | 1 |
| 15T | Ear Drops | 15 ml | 2 |
| 19B | Eye Drops containing Cocaine Hydrochloride | 15 ml | .. |
| 22E | Eye Drops, Other | 15 ml | 5 |
| 23F | Eye Lotions | 200 ml | 2 |
| 29M | Inhalations | 50 ml | 1 |
| 64J | Linctuses containing Codeine Phosphate | 100 ml | .. |
| 34T | Linctuses, Other | 100 ml | 2 |
| 39C | Lotions | 200 ml | 2 |
| 65K | Mixtures containing Codeine Phosphate | 200 ml | .. |
| 66L | Mixtures for Children containing Codeine Phosphate | 100 ml | .. |
| 41E | Mixtures for Children, Other | 100 ml | 4 |
| 40D | Mixtures, Other | 200 ml | 4 |
| 30N | Mouth Washes | 200 ml | 1 |
| 42F | Nasal Instillations | 15 ml | 2 |
| 43G | Ointments, Waxes | 100 g | 1 |
| 44H | Paints | 25 ml | 1 |
| 63H | Pastes containing Cocaine Hydrochloride | 25 g | .. |
| 45J | Pastes, Other | 100 g | 1 |
| 49N | Powders for Internal Use | 100 g | 2 |
| 52R | Solutions | 200 ml | 2 |

# Index of Manufacturers' Code

| Code | Manufacturer |
|---|---|
| **AB** | Abbott Australasia Pty Ltd |
| **AE** | AFT Pharmaceuticals Pty Ltd |
| **AF** | Alphapharm Pty Ltd |
| **AG** | Allergan Australia Pty Limited |
| **AL** | Alphapharm Pty Ltd |
| **AN** | Amgen Australia Pty Limited |
| **AP** | AstraZeneca Pty Ltd |
| **AS** | Aspen Pharmacare Australia Pty Limited |
| **AT** | Actelion Pharmaceuticals Australia Pty Ltd |
| **AV** | sanofi-aventis Australia Pty Ltd |
| **BB** | Blackmores Limited |
| **BD** | Biogen Australia Pty Ltd |
| **BE** | Beiersdorf Australia Ltd |
| **BG** | Sandoz Pty Ltd |
| **BI** | Biotech Pharmaceuticals Pty Ltd |
| **BN** | Bayer Australia Ltd |
| **BQ** | Bristol-Myers Squibb Australia Pty Ltd |
| **BR** | B. Braun Australia Pty Ltd |
| **BV** | BSN medical (Aust.) Pty Ltd |
| **BX** | Baxter Healthcare Pty Limited |
| **BY** | Boehringer Ingelheim Pty Ltd |
| **BZ** | Boucher & Muir Pty Ltd |
| **CC** | ConvaTec A Division of Bristol-Myers Squibb Australia Pty Ltd |
| **CF** | CNS Pharma Pty Ltd |
| **CH** | Apotex Pty Ltd |
| **CJ** | Celgene Pty Limited |
| **CR** | Pharmacor Pty Limited |
| **CS** | Seqirus (Australia) Pty Ltd |
| **CT** | Coloplast Pty Ltd |
| **CU** | Care Pharmaceuticals Pty Limited |
| **CX** | Contact Lens Centre Australia Limited |
| **DE** | Stallergenes Australia Pty Ltd |
| **DJ** | De Fries Industries Pty Ltd |
| **DO** | Aurobindo Pharma (Australia) Pty Limited |
| **DQ** | Church & Dwight (Australia) Pty Ltd |
| **DV** | Medical Developments International Limited |
| **DZ** | Medsurge Healthcare Pty Ltd |
| **EA** | Amneal Pharmaceuticals Pty Ltd |
| **ED** | Amneal Pharmaceuticals Pty Ltd |
| **EF** | Amneal Pharmaceuticals Pty Ltd |
| **EI** | Eisai Australia Pty Ltd |
| **EL** | Eli Lilly Australia Pty Ltd |
| **EO** | Ego Pharmaceuticals Proprietary Limited |
| **ER** | Eris Pharmaceuticals (Australia) Pty Ltd |
| **EU** | Emerge Health Pty Ltd |
| **EZ** | Merz Australia Pty Ltd |
| **FB** | Pierre Fabre Medicament Australia Pty Ltd |
| **FI** | Boehringer Ingelheim Pty Ltd |
| **FK** | A. Menarini Australia Pty Limited |
| **FM** | Fawns and McAllan Proprietary Limited |
| **FN** | Fresenius Medical Care Australia Pty Ltd |
| **FO** | For Benefit Medicines Pty Ltd |
| **FP** | Ferring Pharmaceuticals Pty Limited |
| **FR** | Merck Sharp & Dohme (Australia) Pty Ltd |
| **FX** | Finox Biotech Australia |
| **FZ** | Pfizer Australia Pty Ltd |
| **GA** | Galderma Australia Pty Ltd |
| **GC** | GlaxoSmithKline Australia Pty Ltd |
| **GH** | Amdipharm Mercury (Australia) Pty Limited |
| **GI** | Gilead Sciences Pty Limited |
| **GK** | GlaxoSmithKline Australia Pty Ltd |
| **GN** | Actavis Pty Ltd |
| **GO** | BGP Products Pty Ltd |
| **GQ** | Generic Health Pty Ltd |
| **GT** | BGP Products Pty Ltd |
| **GV** | Amgen Australia Pty Limited |
| **GX** | Apotex Pty Ltd |
| **GZ** | sanofi-aventis Australia Pty Ltd |

| Code | Manufacturer |
|---|---|
| **HB** | Besins Healthcare Australia Pty Ltd |
| **HM** | Meda Pharmaceuticals Pty Ltd |
| **HQ** | Generic Health Pty Ltd |
| **HR** | Paul Hartmann Pty Ltd |
| **HX** | Sandoz Pty Ltd |
| **IA** | iNova Pharmaceuticals (Australia) Pty Limited |
| **IB** | Apotex Pty Ltd |
| **IO** | BioMarin Pharmaceutical Australia Pty Ltd |
| **IR** | Indivior Pty Ltd |
| **IS** | Ipsen Pty Ltd |
| **IV** | iNova Pharmaceuticals (Australia) Pty Limited |
| **IX** | Clinect Pty Ltd |
| **IY** | Clinect Pty Ltd |
| **JC** | Janssen-Cilag Pty Ltd |
| **JJ** | Johnson & Johnson Medical Pty Ltd |
| **JO** | Juno Pharmaceuticals Pty Ltd |
| **JT** | Johnson & Johnson Pacific Pty Limited |
| **JU** | Juno Pharmaceuticals Pty Ltd |
| **KE** | Kendall Australasia Pty Ltd |
| **KI** | KCI Medical Australia Pty Ltd |
| **KP** | Eli Lilly Australia Pty Ltd |
| **KY** | Key Pharmaceuticals Pty Ltd |
| **LL** | Astellas Pharma Australia Pty Ltd |
| **LM** | Link Medical Products Pty Ltd |
| **LN** | Aspen Pharmacare Australia Pty Limited |
| **LO** | Leo Pharma Pty Ltd |
| **LQ** | Astellas Pharma Australia Pty Ltd |
| **LR** | Cipla Australia Pty Ltd |
| **LS** | Astellas Pharma Australia Pty Ltd |
| **LU** | Lundbeck Australia Pty Ltd |
| **LX** | Lawley Pharmaceuticals Pty Ltd |
| **LY** | Eli Lilly Australia Pty Ltd |
| **MF** | Mundipharma Pty Limited |
| **MH** | Molnlycke Health Care Pty Ltd |
| **MK** | Merck Sharp & Dohme (Australia) Pty Ltd |
| **MM** | 3M Pharmaceuticals Australia Pty Ltd |
| **MT** | Mentholatum Australasia Pty Ltd |
| **MW** | Biomed Aust Pty Limited |
| **NE** | Norgine Pty Limited |
| **NF** | Novo Nordisk Pharmaceuticals Pty Limited |
| **NI** | Novo Nordisk Pharmaceuticals Pty Limited |
| **NM** | Novartis Pharmaceuticals Australia Pty Limited |
| **NO** | Novo Nordisk Pharmaceuticals Pty Limited |
| **NQ** | Takeda Pharmaceuticals Australia Pty Ltd |
| **NT** | Nestle Australia Ltd |
| **NU** | Nutricia Australia Pty Limited |
| **NV** | Novartis Pharmaceuticals Australia Pty Limited |
| **OA** | Orphan Australia Pty Ltd |
| **OB** | Oral B Laboratories Pty Ltd |
| **OC** | Accord Healthcare Pty Ltd |
| **OD** | Accord Healthcare Pty Ltd |
| **OE** | Omegapharm Pty Ltd |
| **OH** | Orpharma Pty Ltd |
| **OL** | Owen Laboratories Division of Galderma Australia Pty Ltd |
| **OM** | Colgate Oral Care |
| **ON** | Orion Laboratories Pty Ltd |
| **OS** | Otsuka Australia Pharmaceutical Pty Ltd |
| **OW** | Arrow Pharma Pty Ltd |
| **PE** | Allergan Australia Pty Limited |
| **PF** | Pfizer Australia Pty Ltd |
| **PK** | Fresenius Kabi Australia Pty Limited |
| **PL** | The Trustee for Virgo Unit Trust (trading as Phebra) |
| **PM** | Pharmaceutical Manufacturing Company Pty Limited |
| **PP** | Petrus Pharmaceuticals Pty Ltd |
| **PQ** | PMIP Pty Ltd |
| **PY** | Procter & Gamble Pharmaceuticals Australia Pty Ltd |
| **QA** | Aspen Pharma Pty Ltd |
| **QH** | Cortex Health Pty Ltd |

| Code | Manufacturer |
|---|---|
| **QL** | Amcla Pty Limited |
| **RA** | Sun Pharma ANZ Pty Ltd |
| **RB** | Bio Revive Pty Ltd |
| **RC** | Reckitt Benckiser (Australia) Pty Limited |
| **RF** | Arrow Pharma Pty Ltd |
| **RI** | Dr Reddy's Laboratories (Australia) Pty Ltd |
| **RN** | Sun Pharma ANZ Pty Ltd |
| **RO** | Roche Products Pty Ltd |
| **RW** | Arrow Pharma Pty Ltd |
| **RX** | Servier Laboratories (Aust.) Pty Ltd |
| **RZ** | Dr Reddy's Laboratories (Australia) Pty Ltd |
| **SA** | SciGen (Australia) Pty Limited |
| **SB** | Nutricia Australia Pty Limited |
| **SE** | Servier Laboratories (Aust.) Pty Ltd |
| **SG** | Merck Serono Australia Pty Ltd |
| **SI** | Sigma Company Limited |
| **SN** | Smith & Nephew Pty Limited |
| **SS** | SSL Australia Pty Ltd |
| **SW** | sanofi-aventis Australia Pty Ltd |
| **SY** | Bayer Australia Ltd |
| **SZ** | Sandoz Pty Ltd |
| **TB** | Teva Pharma Australia Pty Limited |
| **TD** | STADA Pharmaceuticals Australia Pty Limited |
| **TF** | Te Arai BioFarma Limited |
| **TK** | Takeda Pharmaceuticals Australia Pty Ltd |
| **TL** | Tolmar Australia Pty Ltd |
| **TM** | Technipro Marketing Pty Ltd |
| **TS** | Specialised Therapeutics Australia Pty Ltd |
| **TW** | Apotex Pty Ltd |
| **TX** | Apotex Pty Ltd |
| **UA** | Actavis Pty Ltd |
| **UC** | UCB Australia Proprietary Limited |
| **UM** | Unomedical Pty Ltd |
| **UN** | Unilever Australia Limited |
| **VE** | AbbVie Pty Ltd |
| **VF** | Vitaflo Australia Pty Limited |
| **VI** | ViiV Healthcare Pty Ltd |
| **VL** | Vifor Pharma Pty Limited |
| **VR** | Vertex Pharmaceuticals (Australia) Pty Ltd |
| **VZ** | Sanofi-aventis Healthcare Pty Ltd |
| **WA** | sanofi-aventis Australia Pty Ltd |
| **XA** | Pharmaxis Ltd |
| **XH** | MS Health Pty Ltd |
| **XI** | Alexion Pharmaceuticals Australasia Pty Ltd |
| **XM** | The Medicines Company (Australia) Pty Limited |
| **YC** | Cipla Australia Pty Ltd |
| **YN** | Mayne Pharma International Pty Ltd |
| **YT** | Mayne Products Pty Ltd |
| **ZA** | AstraZeneca Pty Ltd |
| **ZI** | Shire Australia Pty Limited |
| **ZP** | Medis Pharma Pty Ltd |
| **ZX** | Zenex Pharmaceuticals Pty Ltd |

# Generic/Proprietary Index

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